FINAL DEGREE PROJECT

APPROACHING ELECTIVE COLORECTAL SURGICAL SITE INFECTIONS: BENEFITS OF PERCUTANEOUS RADIO-GUIDED DRAIN PLACEMENT VERSUS SURGICAL REINTERVENTION TO CONTROL THE FOCUS OF INFECTION.

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Vull dedicar aquest treball als meus pares i als meus avis, la meva eterna font de recolzament i suport durant aquests sis anys. A la Dra. Carol Batlle i a la Dra. Ariadna Ruiz, juntament amb tot l'equip de Medicina Interna de l'Hospital J. Trueta per tot l'interès i coneixement que han bolcat en mi durant les pràctiques al servei. I finalment, vull agrair a aquelles persones que Girona ha posat a la meva vida i que sense elles tot aquest camí no hagués estat igual.

Moltes gràcies!

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1. ABSTRACT:

TITLE: "Approaching elective colorectal surgical site infections: benefits of percutaneous radio-guided drain placement versus surgical reintervention" to control the focus of infection.

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BACKGROUND: Surgical Site infections (SSI) are a common complication of any type of surgery, but especially relevant in colorectal surgery (where the incidence goes up to 35% infection rates), due to the clean-contaminated nature of the intervention.

SSI have a great impact in healthcare as they are associated with higher risk of complications, mortality rates, re-admission rates and also increase the length of stay at the hospital of the patients that develop them.

Some studies have analysed populations undergoing colon and rectal procedures to determine risk factors of SSI or current predictors of treatment failure.

Even though there has been a lot of improvement in prevention of the SSI that has translated into a decrease of mortality rates, there are still an important subset of patients that end up developing an infection after surgery. Especially in the organ-space SSI, which usually needs direct drainage or manipulation of the focus of infection apart from the antibiotic therapy.

The aim of the study is to compare the different approaches to resolve an organ-space SSI, once it has developed after an elective colorectal surgery to control the focus of infection: reintervention versus radio-guided drain placement.

OBJECTIVE: The main objective is to compare the impact in mortality, re-admission rates and length of stay of both approaches (surgical re-intervention versus percutaneous radio-guided drain placement) and how they gain control over the focus of infection (via measurement of the "duration of the infection" with the help of serologic parameters such as APR). The evidence gathered may be used to elaborate surgical profiles as to reach optimization in the treatment of the colorectal organ-space surgical-site-infections.

DESIGN AND SETTING: It is designed as a quasi-experimental study, open-label and multicentric, conducted in different hospitals of Catalonia, and with the objective of comparing the different approaches to solve an organ-space surgical site infection: surgical re-intervention versus percutaneous radio-guided drain placement.

PARTICIPANTS AND METHODS: 170 participants will be enrolled using a non-probabilistic consecutive sampling, with a two-year time of recruiting process. The participants will be divided between the intervention and the control group according to a careful surgical and clinical examination of each case performed by the colorectal surgeons and the interventionism radiologist team.

Data about length of stay, mortality rates, re-admission rates, duration of the infection will be evaluated 3 months after the intervention.

KEYWORDS: *Surgical site infection (SSI), organ-space surgical-site-infection (OS-SSI), percutaneous drain placement, colorectal SSI, hypoalbuminemia, comorbidities, mortality rates, length of stay, re-admission rates.*

2. ABBREVIATIONS AND ACRONYMS:

ASA	American Society of Anaesthesiologists
APR	Acute Phase Reactants
BMI	Body Mass Index
C	Clean
CC	Clean-contaminated
CDC	Centre for Disease Control and Prevention
CEIC	Ethics Committee for Clinical Investigation
CI	Confidence interval
CO	Contaminated
CT	Computed tomography
D	Dirty/Infected
DIP	Deep Incisional Primary
DIS	Deep Incisional Secondary
EBL	Estimated blood loss
ESBL-PE	Extended-spectrum beta-lactamase-producing *Enterobacteriaceae*
HAI	Healthcare Associated Infection
HC	Hospital Coordinators
HCP	Healthcare Professionals
IBD	Irritative Bowel Disease
IQR	Interquartile Range
LOS	Length of stay

MDR	Multidrug resistant
MI	Main investigator
MBP	Mechanical Bowel Preparation
NHSN	National Healthcare Safety Network
NNIS	National Nosocomial Infections Surveillance
OAP	Oral Antibiotic Prophylaxis
OR	Operation Room
OS-SSI	Organ-space Surgical Site Infection
PCR	Protein C Reactive
SIP	Superficial Incisional Primary
SIR	Standardized Infection Ratio
SIS	Superficial Incisional Secondary
SPSS	Statistical Package for Social Science
SSI	Surgical Site infection
WHO	World Health Organization

3. INTRODUCTION:

3.1 What is a surgical site infection?

According to the Centre for Disease Control and Prevention (CDC) guidelines, a surgical site infection or SSI can be described as any infection originating in surgical wounds or the organs/spaces opened or manipulated during a surgical procedure within 30 days or a year if an implant is left in place and the infection is thought to be secondary to surgery (1). While advances have been made in infection control practices, including improved operating room ventilation, sterilization methods, barriers, surgical technique, availability of antimicrobial prophylaxis… SSIs remain a substantial cause of morbidity, prolonged hospitalization, and death. The annual cost of SSI in the United States is estimated to be about 3.5 to 10 billion dollars, due to the increased length of stay, emergency department visits and readmissions (2).

It is the most common postoperative complication: the CDC healthcare-associated infection (HAI) prevalence survey found that there were an estimated 110,800 surgical site infections associated with inpatient surgeries in 2015 (3), and it can have an incidence up to 20% depending on the surgical procedure, the surveillance criteria used and the quality of the data collected (4). The rates of SSI are much higher with abdominal surgeries in contrast with other types of surgeries, depending on the level of contamination and the surgical approach, but with several prospective studies indicating incidences of 15 to 25% rates (5,6).

The implementation of surgical checklists and preventive bundles have decreased the rates of SSI and the mortality rates associated with it, but there's still an important by-product incidence in mortality. Depending on the source, incidences may vary a little, from a 3 to 6.5% of 30-day mortality rates and around 7% of 10-year mortality rates after an SSI according to the NSHN (7,8). According to a Spanish multicentre observational prospective cohort study performed in 2017, the overall 30-day mortality of colon surgery was significantly higher than rectal surgery, with incidences 11.5% versus 5.1% (6).

VINCat is an epidemiological surveillance program of infections related to the Catalan healthcare system. It wants to contribute to decreasing infection taxes by promoting a standardized surveillance system, recollect data adjusted for centres and infection risk to compare between territories and other surveillance systems and to find evidence to recognise, prevent and treat them adequately (9).

According to their annual report, in 2022 there were a total of 2.919 colon surgical interventions from which a total of 221 surgical site infections were developed (7.57%), and a total of 1014 rectal surgical interventions, from which a total of 119 SSI was recorded (11.74%).

Throughout the years, SSI incidences after colon surgery have reduced significantly, from rates up to 20% in 2011 to recent rates of 7.69% in 2020 and 6,84% in 2021.

In rectal surgery we can observe the same overall tendency but with rates still a lot higher (22.6% in 2011 to 11.66% in 2020 and 13.63% in 2021) (10). (*See "Annex 16.1)*

The development of SSI is also an important source of patient anxiety after the hospital discharge due to the responsibility for their own wound care. In a prospective 24-month observational study conducted with patients undergoing elective colorectal surgery and followed for 90 days, with serially photographing and clinically characterization of the wound as early as day two post-surgery to diagnose SSI precociously, they presented that from a total of 171 patients only 8% received a diagnosed of SSI by study criteria. Furthermore, only 2% were captured in the database, but 15% of the patients included sought consultation repeatedly (telephone calls, surgical clinic visits, emergency department visits, primary care visits…), demonstrating that commonly in-person evaluation yields to the re-consulting of healthcare resources even though few wounds will be diagnosed of an SSI. The major disturbances acknowledged by patients were incision erythema and the abdominal drainage (11).

Despite the prevention measures applied in the preoperative and postoperative care, a subset of patients will develop an SSI, requiring a multidisciplinary and multifactorial approach that will result in a big impact (economic, mental and personal) (12).

3.2 Types of surgical site infection

Depending on if it is affecting the incision or the deep tissue in the operation site, we can differentiate three entities: a) superficial incisional SSI, b) deep incisional SSI and c) organ-space SSI (3,6,13).

3.2.1 Superficial incisional SSI (13)

All infection that meets the following criteria:

- Date of event occurs within 30 days following the surgical procedure (interpreting that day 1 is the procedure date)
  AND
- Involves only skin and subcutaneous tissue of the incision.
  AND
- The patient has at least one of the following:
  - Purulent drainage from the superficial incision.
  - Organism (s) identified from an aseptically obtained specimen from the superficial incision or subcutaneous tissue by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment.
  - A superficial incision that is deliberately opened by a surgeon, physician or physician designee and culture or non-culture-based testing of the superficial incision or subcutaneous tissue is not performed.
    AND
  - Patient has at least one of the following signs or symptoms: localized pain or tenderness; localized swelling; erythema; or heat.
  - Diagnosis of a superficial incision SSI by a physician or physician designee.

As stated by the National Healthcare Safety Network (NHSN) the following do not qualify as criteria for meeting its definition of superficial incision SSI (3):

- Diagnosis/treatment of cellulitis (redness/warmth/swelling) by itself (it doesn't meet d) criteria)

- A stitch abscess alone (minimal inflammation and discharged confined to the points of suture penetration).
- A localized stab wound or pin site infection, depending on the depth, might only be considered either a skin or soft tissue infection.

It also won't be considered a superficial SSI if the infection is at an episiotomy, a circumcision site or a burn wound; or if the SSI extends into fascia or muscle (14).

We can also describe two specific types of superficial incisional SSIs:

- Superficial incisional primary or SIP: a superficial incisional SSI that is identified in the primary incision in a patient that has had an operation with one or more incisions (for example a C-section or chest incision)
- Superficial incisional secondary or SIS: a superficial incisional SSI that is identified in the secondary incision in a patient hat has had an operation with more than one incision (for example a donor site incision for a coronary bypass graft surgery).

3.2.2 Deep incisional SSI (13)

All infection that meets the following criteria:

- Date of event occurs within 30 to 90 days following the surgical procedure depending on the surveillance periods determined by NHSN operative procedure categories (that fundamentally differ depending on if an implant has been installed in the infection site).
  AND
- Involves deep soft tissues of the incision (for example, fascial and muscle layers)
  AND
- Patient has at least one of the following:
  - Purulent drainage from the deep incision (not originated in an organ/space site)
  - A deep incision that is deliberately opened or aspirated by a surgeon, physician or physician designee or spontaneously dehisces.

- Organism (s) identified from the deep soft tissues of the incision by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment, or culture or non-culture-based microbiologic testing method is not performed.

  A culture or non-culture-based test from the deep soft tissues of the incision that has a negative finding does not meet this criterion (thus, it discards the possibility of SSI presence).

  AND
- Patient has at least one of the following symptoms: fever (>38ºC); localized pain or tenderness.
- An abscess or other evidence of infection involving the deep incision detected on gross anatomical exam, histopathologic exam, or imaging test.

Same as the superficial incisional SSI, we can also differentiate between "deep incisional primary or DIP" and "deep incisional secondary or DIS" depending on in which incision the SSI is identified in (3).

3.2.3 Organ-space SSI (13)

All infection that meets the following criteria:

- Date of event occurs within 30 to 90 days following the operative procedure depending on the surveillance periods determined by NHSN operative procedure categories (that fundamentally differ depending on if an implant has been installed in the infection site).

  AND
- Involves any part of the body deeper than the fascial/muscle layers that is opened or manipulated during the operative procedure.

  AND
- Patient has at least one of the following:
  - Purulent drainage from a drain placed into the organ/space (for example: closed suction drainage system, open drain, etc)

- Organism(s) identified from fluid or tissue in the organ/space by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment.
- An abscess or other evidence of infection involving the organ/space detected on gross anatomical exam or histopathologic exam, or imaging test evidence definitive or equivocal for infection.

AND

- Meets at least <u>one</u> criterion for specific organ-space infection site listed in The Surveillance Definitions for Specific Types of Infections of the NHSN.

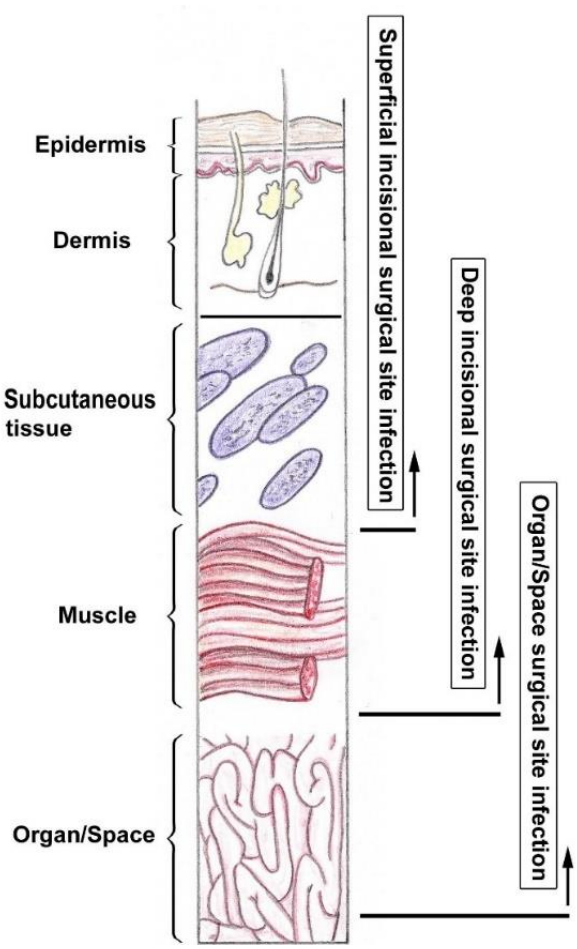

Figure 1. Definition and types of SSI. Extracted from "Wound Infection Clinical Presentation" MedScape (15)

Another tool to assess or describe SSI using objective criteria is the **ASEPSIS score** system, acronym that stands for: **A**dditional treatment, the presence of **S**erous discharge, **E**rythema, **P**urulent exudate, **S**eparation of the deep tissues, **I**solation of bacteria, duration of inpatient **S**tay.

It originally was created to assess sternal wounds from cardiothoracic surgery, but recently demonstrated a higher inter-rater agreement between surgeons compared with the CDC definitions of SSI. It gives additional points for antibiotic treatment, drainage of pus under local anaesthesia, debridement of the wound under general anaesthesia (2,13).

Scores are calculated based on the percentage of the wound affected by each variable, and the total score is grouped into four categories (2):

Satisfactory healing	0-10 score
Disturbance of healing	11-20 score
Minor SSI	21-30 score
Moderate SSI	31-40 score
Severe SSI	>40 score

Table 1. ***Types of SSI according to the ASEPSIS score. Extracted from PubMed*** (2)

3.3 Wound classification (3,14):

It is an assessment of the degree of contamination of a surgical wound at the time of the surgical procedure assigned by a person involved in this procedure (for example: the surgeon, circulating nurse, etc) and is adopted within each organization. The four wound classifications available within the NHSN application are: Clean (C), Clean-Contaminated (CC), Contaminated (CO) and Dirty/Infected (D).

- Clean (C) or class I wounds: surgical wounds uninfected or with no acute inflammation or that have been primary closed within the surgical procedure (closed drainage used if necessary). A clean wound also implies that there hasn't been an entry to the gastrointestinal/urinary/respiratory/biliary tracts. Their risk of infection is <2%.
- Clean-contaminated (CC) or class II wounds: elective entry into respiratory/biliary/gastrointestinal/urinary tracts with minimal spillage and without accidental contamination (no evidence of infection or major break in aseptic technique). Their risk of infection is <10%.
- Contaminated (CO) or class III wound: open wounds with nonpurulent inflammation present, with gross spillage from the gastrointestinal tract or penetrating traumatic wounds with <4h of evolution. Their risk of infection is up to 20%.

- Dirty/infected (D) or class IV wounds: penetrating traumatic wounds of >4h or with days of evolution and devitalization of the surrounding tissues, wounds with purulent inflammation present or preoperative perforation of viscera. Their risk of infection is about 40%.

In a colorectal surgery, the wound cannot be assigned as clean since there's an entry to the gastrointestinal tract (3,14), and that is one of the reasons why colorectal surgeries have slightly more incidence of SSI. While the incisional SSI rates have decreased with the advances in colon and rectal surgery such as laparoscopy and other minimally invasive techniques, they have had a lesser impact on the organ-space SSI (6).

The development of an organ-space SSI has more severe consequences than the development of an incisional-SSI and in many cases requires reoperation and increases not only morbidity but also the length of stay (6).

3.4 Risk factors of SSI

Previous studies have found an association between postoperative adverse events including SSI, and certain patient-related risk factors such as higher American Society of Anaesthesiologists (ASA) physical status classification, increased body mass index, or history of chronic obstructive pulmonary disease. Preoperative chemoradiotherapy and poor compliance with an enhanced recovery program are also associated with higher readmission rates. Furthermore, the emergence of multidrug resistance may negatively impact treatment response in SSI (17).

Other important patient-related factors for SSI include existing infection, low serum albumin concentration, older age, diabetes mellitus and ischemia secondary to vascular disease or irradiation. Physiological states that increase the risk of SSI include trauma, shock, blood transfusion, hypothermia, hypoxia, and hyperglycaemia. Surgical risk factors include prolonged procedure and inadequacies in either the surgical scrub or the antiseptic preparation of the skin. Parameters that may be associated independently with an increased risk of SSI and that may predict infection, include abdominal surgery, a contaminated or dirty operation, and more than three diagnoses at the time of discharge (18).

It has been proposed that incisional SSI and organ space SSI may have distinct pathogenesis and risk factors: incisional SSI has been associated with increased body mass index (BMI) or the presence of an ostomy while organ-space SSI has been more frequently related to blood transfusion, previous abdominal surgery, or poor nutritional status. A multicentre observational prospective cohort study of adults undergoing elective colon and rectal surgeries at ten Spanish hospitals from 2011 to 2014 concluded that comparing both populations overall SSI (either incisional or organ-space) rates were higher in rectal surgery than in colon surgery. Male sex was a common risk factor for developing an SSI in both colon and rectal surgeries (although the reasons are not known) and ostomy creation was a strong risk factor for the development of an organ-space SSI in colon but not in rectal surgery. It is true that patients in this study undergoing colon surgery were older, had more IBD and less laparoscopy, factors related to SSI. The laparoscopy approach significantly reduced SSI rates in several large-database studies and offered other benefits such as faster recovery of pulmonary function, less pain and shorter postoperative stay. On the other hand, patients undergoing rectal surgery were younger but had more rate of malignancy, more frequently received chemoradiotherapy and had longer surgery duration. Probably, the beneficial effect of laparoscopy was exceeded by the higher frequency of risk factors for SSI inherent in rectal surgery. The surgical techniques are also different, something inherent to the anatomical location of the disease, in special with more osteotomies performed in rectal resections. These factors, associated with the fact that the rectum has higher bacterial contamination load, conferred it greater risk of SSI (6).

Although laparoscopy is regarded as a protective factor against SSI, it has been found in some studies that it was an independent risk factor for 30-day treatment failure in incisional-SSI. We must also consider that patients with an organ-space SSI who underwent laparoscopic surgery were younger, had a lower NNIS modified Risk Index, lower ASA score, more frequently received chemotherapy and radiotherapy and were more frequently diagnosed after discharge than those with open surgery (17).

The authors hypothesized that because patients with previous laparoscopy had less comorbidities, they were discharged earlier than those with previous laparotomy, and then they presented with a more severe infection that contributed to treatment failure (17).

3.4.1 Duration of the procedure:

It is the interval in hours and minutes between the "surgery Start Time" and the "surgery Finish Time": interval between the procedure is begun (for example performing the incision for the surgical procedure) and the end of the surgery (time when all instruments are counted and verified as correct, postoperative radiologic studies to be done in the OR are completed, all dressings and drains secured, etc) (3).

When the procedure is bilateral, the total duration of the procedure is divided in half.

To calculate the surgical risk, we consider the value obtained in the 75% interquartile, according to the NHSN program. That means we choose as a time reference a value that is equal or higher than the 75% of data from the 100% collected, and only 25% of the data is above it. According to VINCat, the 75 percentile of the duration of the procedure for colon surgeries is of 180 minutes and 252 minutes for rectal surgeries.

If the length of the surgical procedure is longer than its expected duration in the program, we must add one more point in the risk index calculator (13).

In the Spanish multicentre observational prospective cohort study we mentioned before, even though the duration of the procedure varied between colon and rectal populations, the outcome of patients that developed an SSI showed no significant differences, neither in readmission rates nor in the length of stay (6).

3.4.2 ASA Physical Status Classification System:

The purpose of the system is to assess and communicate a patient's pre-anaesthesia medical comorbidities. The classification alone does not predict the perioperative risks but used with other factors (such as type of surgery frailty, etc) it can be helpful in predicting perioperative risks (19).

In the Spanish multicentric observational prospective cohort study we mentioned before, the patients who underwent colon surgery were older and had higher proportions of ASA score than patients undergoing rectal surgery: 42.18% of patients undergoing colon surgery had an ASA of III-IV versus a 36,69% of patients undergoing rectal surgery (6).

ASA I	Healthy patients
ASA II	Mild to moderate systemic disease
ASA III	Sever systemic disease which limits activity (substantive functional limitations) but isn't incapacitating
ASA IV	Severe incapacitating disease process that is a constant threat to life
ASA V	Moribund patient not expected to survive >24 hours without the operation
ASA VI	Declared brain-dead patient whose organs are being removed for donor purposes

Table 2. ASA Physical Status Classification System. Extracted from the American Society of Anaesthesiologists. (19)

3.4.3 Surgical antimicrobial prophylaxis:

The surgical antimicrobial prophylaxis refers to the use of antibiotics for the prevention of surgical site infections (20), during the surgery or in the first 24h after the surgical procedure (13).

Each hospital must have a guide with specific recommendations for each type of intervention, as to categorize the realization of this prophylaxis as adequate or not adequate. We can consider it adequate when the following criteria is met (13,20):

a) the choice of antimicrobial drug must align with what our hospital recommendation guide suggests or in its defect, what the surgical team recommends

b) right timing of administration; the first dose must be given within 60 minutes of incision (the timing can vary depending on the route of administration: with continuous perfusion must be given within 30 minutes, while in bolus within 10 to 70 minutes before the procedure; depending on the drug of choice) and

c) the prophylaxis must not exceed 24h after the surgical procedure.

The effective use of antimicrobials to prevent infection is essential to reduce risks associated with surgical procedures, but efforts need to be made to maximise the quality of the prophylaxis prescribing (20).

The use of oral antibiotic prophylaxis (OAP) was discontinued in most Spanish hospitals due to reasons not well established even though in other European and American countries the administration of OAP is a daily practice. In the Spanish multicentre observational prospective cohort study, we mentioned before, even though the administration of OAP was not mandatory, and it was done according to local protocols at each hospital, it was applied in four out of ten participating hospitals. When analysing the data, patients who received OAP combined with correct intravenous antibiotic prophylaxis showed significant differences in the overall SSI rate between colon and rectal surgery (a drop of 7.2% rate of incidence: from 19.9% rate to a 12.3%), while there were no significant differences in the rate of organ-space SSI (6). No randomized controlled trials focused upon the comparison between OAP alone versus no preparation, with evidence arising from patients included in two cohort studies, which reduced the incidence of SSI versus no preparation (21).

3.4.4 Mechanical Bowel preparation (MBP):

The role of mechanical bowel preparation (with polyethylene glycol or sodium phosphate) has been studied in randomized controlled trials with perceived benefits including ease of manipulation of the bowel, reduced spillage, and resultant contamination, reduced luminal pressure, and lesser bacterial load. However, recent metanalysis found that the administration of MBP did not impact upon postoperative morbidity or mortality. The American Society for Enhanced Recovery Guidelines and the National Institute of Health and Care suggest that MBP should not be administered routinely, but they recommend the routine use of an isosmotic bowel preparation and combined oral antibiotic prior to elective colorectal surgery (21).

The administration of MBP in most Spanish hospitals was discontinued in the last decades due to the lack of effectiveness (6).

There are a lot of studies (ranging from multicentre trials to single-surgeon trial) that showed contradictory results when talking about the role of MBP in preventing SSI: some studies reported no difference in infectious complications when comparing MBP versus no preparation, while some reported a lower risk or even reported increased morbidity and infectious complications (22).

The use of mechanical bowel preparation added to OAP versus only MBP was associated with a significant reduction in SSI (according to data extracted from 26 randomized control trials and 9 cohort studies), nevertheless the use of MBP with OAP versus only OAP (considered in 2 randomized controlled trials and 2 cohort studies) was not associated with any significant difference in the incidence of SSI (21,22).

3.4.5 Poor nutritional status and hypoalbuminemia:

Preoperative hypoalbuminemia is an independent risk factor for postoperative SSI, increasing the risk of developing an infection sixfold. It also reflects on the severity of the infection; in a study of 524 patients who underwent gastrointestinal surgery, 83.3% of the patients with a serum albumin level below the 30mg/dL developed an organ-space SSI. It is also associated with poor tissue healing, and decreased collagen synthesis, causing delaying in the cicatrisation and healing (23).

3.5 Usual pathogens and multidrug resistance:

In many SSI, the responsible pathogens originate from the patient's endogenous flora. Numerous patient-related and procedure-related factors influence the risk of SSI, and hence prevention requires a "bundle" approach, with systematic attention to multiple risk factors, to reduce the risk of bacterial contamination and improve the patient's defences.

The CDC guidelines for the prevention of SSI emphasise the importance of good patient preparation, aseptic practice, and attention to surgical technique; antimicrobial prophylaxis is also indicated in specific circumstances (4). Recognition of the spectrum of the potentially involved pathogens is crucial for determining correct antibiotic prophylaxis.

In a retrospective study conducted in 2018 the most frequently isolated bacteria were *Enterobacteriaceae* (64.1%), anaerobic rods (61.8%), Gram-negative bacilli (*Pseudomonas aeruginosa)* and *Candida spp* specially during left-side resections (in comparison with right-side resections, in which isolation of *Pseudomonas* and gram-positive cocci excluding enterococci differ in frequency). However, we must take into account that in 28.2% of the patients in this study peritonitis was present at the time of the primary resection because of their causative diseases (24).

According to the annual report from VINCat, in 2022 the most common isolated microorganisms in colon surgery were Gram-negative bacilli (*Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa and Enterobacter cloacae)* with a 38.67% incidence, followed by Gram-positive cocci (*Enterococcus faecium, Enterococcus faecalis and Methicillin Sensible Staphylococcus Aureus)* and then fungi (*Candida albicans and Candida spp*). Less commonly, we'll find anaerobium bacteria or polymicrobial infections. The same happens in rectal surgery (10).

In a multicentric prospective cohorts study conducted in 3 hospitals in Israel, Switzerland and Serbia tried to prove how the risk of developing an SSI in patients undergoing elective colorectal surgery is modified whether the patient is a MDRO-carrier or not. The prevalence of ESBL-PE carriage in their study was 13.8% from a total of 3600 patients that were screened, and the overall incidence of SSI was 15.7%, being higher in the ESBL-PE carriers (24.8%) than non-carriers (11.1%) with an odds ratio of 2.40 (IC 95%: 1.54-3.74). Routine antibiotic prophylaxis of SSI is a third generation cephalosporin with metronidazole, which doesn't cover cephalosporin-resistant bacteria, and that's why carriers of ESBL-PE have a risk two times higher than non-carriers, and in these patients that ESBL-PE identified microorganism were more likely to be the causative pathogen in the SSI (25).

3.6 Calculation of the SSI risk:

There is no specific scoring system to predict the risk of SSI after resection of the colon or rectum (26).

The VINCAT surveillance program uses the same method as the NHSN, which is the Standardized Infection Ratio or SIR; a primary summary measure to track healthcare-associated infections. They assign points based on:

- ASA > III
- Surgical procedure with accidental contamination or infected wound (according to the wound classification by the CDC)
- Surgical procedure with a duration greater than the 75 interquartile for this type of surgery.

The use of laparoscopy modifies the risk of SSI in some types of surgical procedures such as colon surgeries, in which it has been demonstrated that it diminishes the risk of overall developing an SSI (11).

In an American study that identified 1744 patients undergoing pancreatic, hepato-biliary, and colorectal resections between 2010 and 2013 at John Hopkins Hospital they elaborated a 10-point SSI scoring system that incorporated perioperative risk factors such as: blood transfusion, EBL, tachypnoea, and type of surgical procedure, and it was able to stratify the infection risk among patients undergoing abdominal surgery with moderate accuracy. However, there are more factors (not only clinical and operative) but also social and contextual that may impact a patient's risk to develop an SSI (12).

3.7 Bundle of measures to prevent SSI:

Infection prevention strategies must focus on patient-modifiable risk factors such as reduction of bacterial burden and optimization of the surgical environment (27).

The World Health Organization (WHO) elaborated the "Global Guidelines for the Prevention of the Surgical Site Infection (2016)" and summarized in "Do the right thing at the right time to prevent surgical site infections" recommendations during: pre-operative, intra-operative and post-operative period (28). *(See Annex 16.2)*

At our hospital, Josep Trueta of Girona, the preparation for a colorectal intervention implies the following (29):

- a bland, with low residue, diet the previous four days of the surgery (rice, soup, pasta and grilled meat or fish)
- mechanical bowel preparation
- antibiotic prophylaxis with neomycin and metronidazol

After the surgery, in the PREVINQ-Cat register (from the SSI protocol of VINCat) must be specified the following (13):

- Adequate skin shave
- Adequate skin asepsis with alcohol chlorhexidine 2%
- Glycemia levels at the end of the intervention
- Use of warming measures throughout the surgery
- Axillar temperature at the end of the intervention

3.8. Diagnosis of the SSI:

Accurate diagnosis of the SSI depends on the type of procedure performed, and early detection is of great importance for an optimal management of it.

Superficial incisional SSI	Can be fully evaluated through direct observation of the wound.
If there is concern for involvement of underlying tissues in the wound or organ/space, we can recur to imaging.	
Deep incisional SSI	Ultrasound can identify the presence of fluid in the subcutaneous tissues.
Organ/space SSI	In the setting of organ space SSI, computed tomography and magnetic resonance imaging provide a more detailed evaluation of the underlying soft tissue and organ-space.

Table 3. ***Methods of SSI diagnosis depending on type. Based on the "Overview of the evaluation and management of surgical site infection".*** (30) ***Own elaboration.***

Although incisional infections are mostly detected post-discharge, organ space infections occur early in the postoperative course (27).

A Gram stain and culture should be obtained to document the causative organisms, whether there is a wound opening present upon initial evaluation or whether the wound has been opened for initial diagnosis and management upon the suspicion of an SSI.

We must consider that sampling from the skin wound will reflect as a polymicrobial growth, and it will make more difficult to distinguish colonization from true infection; but sampling and obtaining cultures during surgical debridement or obtaining purulent drainage via a radiographically placed drain will be of more use to guide empiric therapy.

If systemic signs of infection are present, concomitant blood cultures should be also obtained. The specificities and sensitivities we will obtain from theses cultures will be used to narrow empiric antibiotics to a specific treatment (30).

3.9. Management of the SSI:

The management of the SSI includes antibiotic therapy, collection drainage, and wound debridement as appropriate. Specific wound management thereafter depends on the location and nature of infection (27).

3.9.1. Wound exploration and debridement:

The treatment of either suspected or confirmed superficial/deep incisional SSI involves opening the wound, draining the infected fluid (which should be cultured) and debridement of the necrotic and devitalized tissue, imperative for adequate treatment (as devitalized material might harbour bacteria).

When imaging determines an undrained fluid collection in communication with an abdominal fascial closure or in cases when the risk of SSI is high, opening the wound is favoured over percutaneous drainage. Antibiotics are required in the setting of the SSI: presence of systemic signs and symptoms of infection.

Deep SSI in abdominal wounds is a major risk for fascial dehiscence and may require emergency exploration of the wound in the operating room to safely debride deeper tissue given the risk of evisceration and to facilitate abdominal exploration.

If the deepest level of infection extends into the abdominal cavity (organ/space SSI), abdominal exploration combined with percutaneous drainage of abscesses inaccessible during laparotomy may be necessary to obtain the source control prior to definitive fascial closure.

Organ/space SSI is different from superficial or deep SSI, with higher morbidity and mortality rates. Computed tomography or ultrasound can be used to guide placement of closed suction percutaneous drains into abscess collections when possible; even though it can be challenging in some cases to differentiate an abscess from an anastomotic leak. The distinction is critical as achieving control of the focus of infection may require additional percutaneous drains, reducing the afferent gastrointestinal flow through complete bowel rest and/or proximal stoma diversion, and/or intra-abdominal re-exploration and washout (27,30).

3.9.2. Antimicrobial therapy:

Antibiotics will be required in the presence of surrounding cellulitis, systemic signs, and symptoms of infection. While they will not always be necessary to treat a superficial SSI, they are nearly always required to treat deep and organ/space SSI.

Clinical circumstances in which we will start antibiotics:

- Surrounding cellulitis
  o Cellulitis associated with intact but indurated surgical incision (even if there is absence of a wound drainage or subcutaneous fluid collection)
  o Persistent cellulitis in the surrounding skin after wound opening
  o Subcutaneous or deeper tissue has persistent inflammation after debridement or drainage (for example, when the source control is not achieved)

- Implanted material present within the infected area (*vascular grafts, orthopaedic hardware)*
- Systemic signs of infection present (>38ºC, white blood cell count >12000)
- Septic shock is persistent despite source control

Table 4. List of clinical circumstances in which we will start antibiotics. Extracted from "Overview of the evaluation and management of the surgical site infection". (30)

The definitive antimicrobial treatment is guided by the clinical response of the patient and results of the wound culture and sensitivities when available.

In the absence of retained foreign material, antibiotics should be stopped with the resolution of cellulitis and/or normalization of physiologic parameters such as fever, leukocytosis, provided the patient is afebrile. In the case of intra-abdominal organ/space infection, antimicrobial treatment can be discontinued four days after source control (30), as shorter courses of antibiotics could decrease the risk of antimicrobial resistance. The STOP-IT trial, in which 518 patients with complicated intrabdominal infection and adequate source control were randomly assigned to either receiving antibiotics until 2 days after the resolution of fever, leukocytosis and ileus (with a maximum length of treatment of 10 days) or either to receive a fixed course of antibiotic for 4±1 days. The study concluded that patients had very similar outcomes despite the group assigned via randomization, hypothesizing that the beneficial effects of systemic antimicrobial therapy were limited to the first few days after intervention (31).

3.9.3 Wound management:

The basic principles of treatment for the wound opened due to SSI is healing by secondary intention with repetitive washouts throughout the day, performed by the nursing team, to decrease microbial wound burden. The disadvantages of healing by secondary intention is the prolonged time to wound healing, as well as painful and cumbersome wound care for the patient (30).

4. JUSTIFICATION:

Surgical site infections are the most common post-operative complication, especially in elective colorectal surgeries due to the clean-contaminated nature of the wound, with several prospective studies indicating an incidence from 15% and up to 25% rates (5,6).

In Catalonia, in 2022 there were a total of 2.919 colon surgical interventions from which a total of 221 surgical site infections were developed (7.57%), and a total of 1014 rectal surgical interventions, from which a total of 119 SSI was recorded (11.74%). Throughout the years, SSI incidences after colon and rectal surgery have reduced significantly, especially the first, from rates up to 20% in 2011 to recent rates of 6,84% in 2021. In rectal surgery the incidence of SSI is still a bit higher, around the 15% rates (10).

So, even though there have been lots of innovations in surgical techniques, operation ventilation and aseptic techniques, a subset of patients will still develop an SSI. This is the reason why it is important to take into account the efforts to prevent, diagnose and treat SSI require a multidisciplinary and multifactorial approach to limit and potentially prevent the great impact in our healthcare system, as they increase morbidity rates, median length of stay in hospitals, re-admissions rates and overall mortality rates (12).

It also implies great economic repercussions in healthcare, as it's been estimated that in the United States the annual cost of SSI is estimated to be about 3.5 to 10 billion dollars, due to the increased length of stay, emergency department visits and readmissions (2).

A lot of studies have focused in recognizing and describing risk factors that can facilitate the development of an SSI as to enhancing its prevention in the perioperative process.

Once developed, most SSIs can be treated with antibiotics, but often to control de focus of infection and resolve the problem there's need of additional surgery or procedures. In the organ-space SSI (OS-SSI), which are the most severe type of SSI, there are essentially two treatment options to control the focus of infection: either via draining the abscess with a radio-guided percutaneous procedure and installation of a drainage or via a re-intervention (27,29).

As of right now, the decision of how to approach an SSI is entirely up to the clinical judgment of the surgeon in charge and, of course, up to the experience of the surgical team in each area (the accessibility of the site of the infection, for example). In some studies, reoperation was found to be a risk factor for treatment failure, probably because it was a surrogate marker of illness severity rather than a risk factor for itself, being decided as the needed approach in most cases of anastomotic leakage to achieve a clinical cure (17).

The aim of this study is to compare both methods to approach an organ/site SSI, considering the numerous co-morbidities and risk factors of each patient, the reason behind the surgery and all the variables that may also increase mortality rates and decrease quality of life. One of them being hypoalbuminemia, that reflect the nutritional status of the patient, and is a risk factor for a patient to develop fascial disruption or dehiscence of the wound (23).

We will evaluate the mortality, re-admission rates and length of stay for each patient. The evidence gathered in the study can be used to create “surgical profiles” and protocolize which intervention (and under which circumstances and comorbidities) will be more beneficial for each patient, individualizing the technique to control the focus of infection as to optimize the resolution of SSI and obtain the best prognosis possible for each case.

5. HYPOTHESIS:

5.1 Main hypothesis:

1) The use of a radio-guided drainage system to treat an SSI developed after an elective colorectal surgery, will decrease mortality rates compared to surgical reintervention.

5.2 Secondary hypothesis:

2) The use of a radio-guided drainage system to treat an SSI developed after an elective colorectal surgery will have lesser re-admission rates compared to surgical reintervention.

3) The use of a radio-guided drainage system to treat an SSI developed after an elective colorectal surgery will reduce the length of the stay of the patients compared to those patients managed with surgical reintervention.

4) The use of a radio-guided drainage system to treat an SSI developed after an elective colorectal surgery will gain control of the infection earlier than a re-intervention.

5) Hypoalbuminemia will worsen the prognosis of the patient with SSI, increasing mortality rates and length of stay (LOS).

6. OBJECTIVES:

6.1 Primary objective:

1) To compare mortality rates in patients older than 18 years old undergoing elective colorectal surgery that evolve a SSI depending on whether the source control is achieved with the use of a radio-guided drainage system against re-intervention.

6.2 Secondary objectives:

2) To compare the length of stay in patients older than 18 years old undergoing elective colorectal surgery that developed an SSI when the infection is controlled with the use of a radio-guided drainage system against re-intervention.

3) To compare re-admission rates in patients older than 18 years old undergoing elective colorectal surgery that developed an SSI that developed an SSI when the infection is controlled with the use of a radio-guided drainage system against re-intervention.

4) To compare control of the infection via acute phase reaction parameters in patients older than 18 years old undergoing elective colorectal surgery that developed an SSI that developed an SSI when the infection is controlled with the use of a radio-guided drainage system against re-intervention.

5) To compare mortality rates and length of stay in patients with hypoalbuminemia in patients older than 18 years old undergoing elective colorectal surgery that developed an SSI after any kind of intervention to control the focus of infection.

7. SUBJECTS AND METHODS :

7.1 Study design:

This project is designed as a **multicentric quasi-experimental study,** to compare both approaches to resolve an SSI: the percutaneous radio-guided drainage system versus the surgical re-intervention, in favour of the former.

Participants will be divided in two groups: radio-guided drainage (intervention group) and re-intervention (control group) based on the judgment of the surgical and the interventionism radiologists' teams, in charge of them in each hospital (taking into account the proximity and accessibility of the SSI to drain percutaneously, the experience and knowledge of each team, etc) assuming that the two groups will be non-equivalent, because participants will not be assigned based on randomization.

It will be a multicentric study as it will recollect data from patients in more than one hospital all over Catalunya.

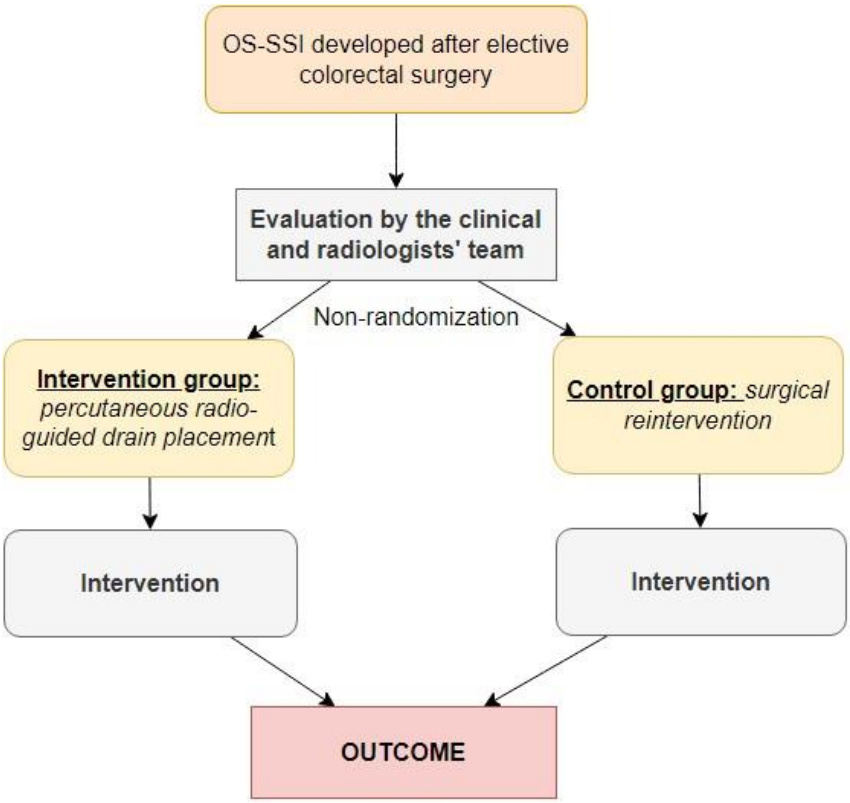

Figure 2. Study setting diagram. Own elaboration.

OS-SSI: organ-site surgical-site-infection

Considering the annual incidence of organ-space surgical site infections in the context of colorectal interventions, the recruitment of patients will last approximately 24 months to gather a sample big enough, with a subsequent follow-up of each patient for 3 months to determine: *length of stay, mortality and re-admission rates, and the duration of infection*. (*See "Variables and measurement").*

After the participants of each group are intervened, we will count the days of hospital admission until the day of the discharge (day one being the day of the intervention). Afterwards, during the three months of follow-up the research team will keep in contact with the participants, as to obtain all re-admissions data (also recorded in the clinical history of each patient in the hospital admitted) and incidence of mortality at the end of the data collection stage of the study. (*See "Follow-up" and "Study Stages").*

The study will end after the statistical analysis and the conclusion.

7.2 Study setting:

The study will be multicentric and carried simultaneously in hospitals of different health regions all over Catalonia with the tools and spaces to offer both types of intervention.

All of them have been chosen because they offer a public service and have the capability to offer both approaches to control the focus of infection; as they have an interventional radiology team with experience in the area to perform this invasive drain placements procedures as well as a general surgery specialisation with a colorectal surgical team with experience in the treatment of organ-space surgical-site-infections.

It is important that they also have direct access to the related specialisations that may be needed if an acute or emergency arises:

- **Intensivist** if major complications regarding the patient's health appear, requiring admission to Intensive Care Unit (ICU).

The interventions will either be done in the operating room (in case of the control group or surgical reintervention) or in the interventional radiology area (in case of the intervention group or radio-guided drain placement will be installed).

7.3 Study population:

The enrolment in the study starts with the diagnosis of an organ-space surgical-site-infection after an elective colorectal surgery. There are basically two scenarios or eligibility moments in which the development of a surgical-site-infection in the context of a post-operative patient can be assessed:

- **Eligibility 1:** during the admission of the patient in the hospital, in the immediate post-operative care after the intervention, when clinical symptoms of an organ-space SSI are identified, and the patient is diagnosed of an OS-SSI.
- **Eligibility 2:** after hospital discharge but comprised in the 30-day post-surgery, when symptoms may arise. Those may be reported either at the visit to his basic health area or due to a consult to the emergency room. Either way, the patient is diagnosed with an OS-SSI.

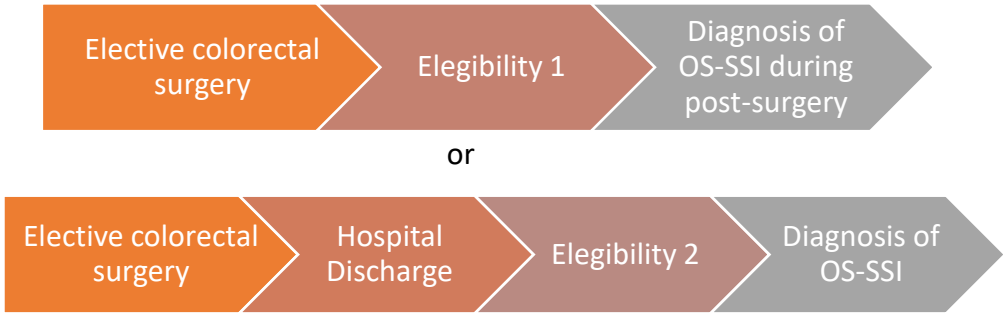

Figure 3. Moments of eligibility to participate in the study. Own elaboration

The selection of subjects will be based on all the patients that meet all the requirements in the inclusion criteria and none of the exclusion criteria.

7.3.1 INCLUSION criteria:

- Patients older than 18 years old.
- Patients that have had an elective colorectal surgery.
- Patients that have developed an organ-space surgical site infection.
- Patients that have signed the informed consent, and they want to participate in the study.
- Patients that can do a follow-up for a period of three months' time after the surgery.

7.3.2 EXCLUSION criteria:

- Patients that had signs of infection in the moment of the intervention (peritonitis, infected diverticulitis, etc)
- Non-availability of complete clinical history
- Patients that have had an urgent colorectal intervention.
- Patients that are not able to carry out an adequate post-treatment follow-up.

7.4 Sampling

7.4.1 Sample size:

According to the National Healthcare Safety Network Surgical Site Infection survey from January 2023, the mortality rates in SSI are 2-to-11-fold higher compared to the patients that do not suffer an SSI (3). Currently, the incidence of mortality of patients suffering of SSI in the 30-day post-surgery period is about 3 to 6.5% rising up to 7% in the next following 10 years (7,8). According to Spanish multicentre observational prospective cohort study performed in 2017, the overall 30-day mortality of colon surgery was significantly higher than rectal surgery, with incidences 11.5% versus 5.1% (6).

In a two-sided or bilateral test, accepting an alpha risk value equal of 0.95 and beta risk value of 0.20 with the approximate 0.11 mortality rates established earlier and a 0.05 value as the minimum difference we want to detect in the comparison of both approaches in favour of the radio-guided drain placement we need a total of 76 patient in each group. If we consider a 10% risk of follow-up loss or risk of study drop-out, then the sample size needs to be 85 patients in each group.

Since the mortality rates we have are from surgical-site infections in total and we do not know their incidence from the outcomes specifically for each type of intervention in the context of an organ-space surgical-infection after an elective colorectal surgery, a re-calculation of the sample size must be done after the data collection of the 20% of the patients enrolled.

7.4.2 Sample selection and recruitment time:

According to the VINCAT register, last year (2022) a total of 152 organ-space surgical infections were registered after colon surgeries and a total of 79 after rectal surgeries in all Catalonia (10).

Knowing we need a total of 170 patients (85 patients in each group), the estimated recruitment time will be approximately 18 months, 1.5 years, in which period we would meet the number of patients needed. *(See Annex 16.1)*

During this period of time, we will explain the purpose of the study to each patient being admitted for an OS-SSI or being diagnosed of an OS-SSI while admitted in the hospitals that have agreed to participate.

A **non-probabilistic consecutive method** of recruitment will be used in the study.

- In the moment of the OS-SSI diagnosis we will present the aim of the study and provide the informative document with further information, carefully explained *(See Annex 16.3 and 16.4)* and ask for any questions or uncertainties.

We will only give the informative document to those patients that already meet the inclusion criteria and will have a short time of reflexion as it is essential to treat the SSI as soon as possible.

- Once explained and being asked about all doubts and uncertainties, the patient will be given the IC document *(See annex 16.5 and 16.6)*.

It is highly important to make sure the patient understands the participation in the study is voluntary, confidential and that he has the right to withdraw of the study at any time.

Once the patient signs the form, he is included in the sample. We will repeat the process as many times as necessary until we obtain an enough sample size according to the calculations made earlier.

As we are estimating the time of recruitment based on last year's recollected data and the incidence of OS-SSI can experience variations over time, the recruitment time can be adjusted considering the enrolment rates during the first months of the study.

Also, as we've mentioned before, the sample size will need to be recalculated once 20% of the participants are enrolled and their data collected, since we do not know exactly the incidence in the group chosen for this study (patients who had developed an OS-SSI after a colorectal elective surgery).

In conclusion, the time of recruitment may vary slightly, depending on the results of the recalculation and the enrolment rates during the first months of the study.

7.5 Variables and measurements

7.5.1 Independent variable

The intervention of the study is the approach method to control the focus of infection in the context of an OS-SSI. It is conceived as a **dichotomous qualitative variable** expressed as:

- Percutaneous radio-guided drainage intervention (**intervention group**)
- Surgical re-intervention (**control group**)

7.5.2 Dependent variables:

MAIN DEPENDENT

The main dependent variable is the **mortality rate**.

The mortality rate is a **continuous quantitative variable**. The measuring instrument will be the database and register we will keep of each patient included in our sample.

SECONDARY DEPENDENT

The other dependent variables we will consider are:

- **Re-admission rates**

This variable will be considered a **continuous quantitative variable** that we will compare between both groups.

The measuring instrument will be the database or register we will keep of each patient included in our sample.

- **Length of stay (LOS)**

The length of stay is considered a **discrete quantitative variable** that will reflect the number of days admitted in the hospital for each patient.

To measure the LOS, we consider **Day one** the day the intervention to control the focus of infection has been applied (independent of which group the participant has assigned to), and count from there until the day of the patients' discharge.

- **Duration of the infection**

The duration of infection is a **discrete quantitative variable** expressed in number of days until the infection parameters get back to normal and there is no presence of clinical symptoms of infection.

To measure and evaluate the period in which the infection is resolved due to the intervention, we will use a few serologic markers to reflect the state of the infection below. All serologic markers will be evaluated with a daily simple analysis of a blood sample. We also will use the presence or absence of fever as a clinical parameter.

- **CRP:**

C Reactive Protein (CRP) is a continuous quantitative variable, but in this study, we will consider it a **nominal dichotomous qualitative variable** with possible values: below 0.5 mg/dL and above 0.5 mg/dL.

- **Procalcitonin**

Procalcitonin is a continuous quantitative variable, but in this study, we will consider this variable a **nominal dichotomous qualitative variable** with possible values: below 0.5 ng/mL and above 0.5 ng/mL.

- **Leukocytes**

White blood cells are considered a continuous quantitative variable, but in this study, we will treat the variable as a **nominal polytomous qualitative variable** with possible values:

  - Below 4.5 $x10^3$ per microliter
  - 4.5 $x10^3$ to 11 $x10^3$ per microliter
  - Above 11 $x10^3$ per microliter

- **Fever:**

This variable will be considered a **nominal dichotomic qualitative variable** which possible values: yes (presence of fever) or no (absence of fever), considering fever any temperature equal or above 38ºC.

	Variable		Type of variable	Values or data
Independent variable	Intervention to control the focus of infection in SSI		Nominal dichotomic qualitative	Percutaneous radio-guided drainage / surgical re-intervention
Main dependent variable	Mortality rates		Continuous Quantitative	Rates of mortality after group of intervention (%)
Secondary dependent variables	Length of stay (LOS)			Number of days of admission since the intervention
	Re-admission rates			Rates of re-admission after group of intervention (%)
	Duration of infection	CPR	Nominal dichotomic qualitative	Below 0.5 mg/dL and above 0.5 mg/dL
		Procalcitonin	Nominal dichotomic qualitative	Below 0.5 ng/mL and above 0.5 ng/mL
		Leukocytes	Nominal polytomous qualitative	Below 4.5 $x10^3$ / 4.5 $x10^3$ to 11 $x10^3$ /above 11 $x10^3$
		Fever	Nominal dichotomic qualitative	Absence of fever / Presence of fever

***Table 5.** Variables and measurement (I). Independent and dependent variables: type and values. Own elaboration.*

7.5.3 Covariables:

The are other variables that can affect the dependent and independent variables, acting as confounders.

- **ASA score**

This variable is defined by the American Society of Anaesthesiologists and reproduces the patient's pre-anaesthesia medical comorbidities and predicts the risk those comorbidities reflect on the surgical intervention (19).

Depending on the presence of systemic disease and the severity of it or the impact on the quality of life for each patient, there are six ASA grades: from the first one indicating a healthy patient to the sixth one indicating a declared brain-dead patient.

Even though it's a discrete quantitative variable, for **our study we will consider the ASA score a nominal dichotomous qualitative variable,** with values: I-III ASA grade or III-VI ASA grade.

- **Age**

It is a discrete quantitative variable measured in years, but that we will categorise in two intervals, turning it into a **nominal dichotomous qualitative variable** with values: 18 to 65 years or above 65 years.

- **Sex**

It is a **nominal dichotomous qualitative variable** with possible values: female or male.

- **BMI**

The body mass index or BMI is a **polytomous qualitative variable**, with a range of different group values:

- Below 18.5: underweight
- 18.5-24.9: healthy weight
- 25-29.9: overweight
- Above 30: obesity

For our study we will consider the following group of values: below 25, 25-30 and above 30.

- **Diabetes mellitus**

The variable of diabetes mellitus will be considered a **nominal dichotomous qualitative variable,** as its possibles values will be presence (yes) or absence (no) of the pathology.

- **Renal failure**

To approximate the accurate renal function, we will use a few serologic markers:

- **Creatinine (Cr):**

Levels of creatinine vary depending on muscle mass, being often lower in women. We will consider the parameter as a **nominal dichotomous qualitative variable** with possible values: 0.6 to 1.3 mg/dL or above 1.3 mg/dL.

- **Urea:**

Levels of urea also vary depending on the age of the patient, but we will consider the parameter a **nominal dichotomous qualitative variable** with possible values: 6 to 24 mg/dL or above 24 mg/dL.

- **Glomerular filtration rate according to CKD-EPI (Chronic Kidney Disease Epidemiology Collaboration):**

We consider a normal eGFR (glomerular filtration rate) > 90 ml/min/1.73m^2. We will consider this variable as a **nominal polytomous qualitative variable** with possible values:

  - >90 ml/min/1.73m^2
  - 60-90 ml/min/1.73m^2
  - 30-59 ml/min/1.73m^2
  - <30 ml/min1.73m^2

- **Reason for the colorectal elective surgery:**

We will consider this covariable a **nominal polytomous qualitative variable** with possible values: neoplasia, inflammatory bowel disease (IBD), others.

- **Immunosuppression**

We will consider presence of immunosuppression:

- If the patient is either taking glucocorticoids at dosage more than 20 mg/24h for more than a month or glucocorticoid at any dosage for more than three months.
- Recipients of solid organ transplant
- Patients receiving chemotherapy
- Patients treated with anti-TNF alpha
- Recipients of bone marrow transplant
- AIDS

This variable will be considered a **nominal dichotomous qualitative variable,** as its possibles values will be presence (yes) or absence (no) of this morbidity.

- **Previous abdominal surgery**

This variable will be considered a **nominal dichotomous qualitative variable,** as its possibles values will be presence (yes) or absence (no) of this morbidity. We understand presence of previous abdominal surgery, any surgery that the patient has had throughout his life.

- **Previous abdominal radiotherapy:**

This variable will be considered a **nominal dichotomous qualitative variable,** as its possibles values will be presence (yes) or absence (no) of this morbidity.

- **Albumin**

Albumin it's a serologic marker that reflects the nutritional status of the patient. Values of albumin are stratified and grouped in different ranges:

- Below 30 g/L: hypoalbuminemia
- 30-35 g/L: normal values

- Above 35 g/L: hyperalbuminemia

We will consider this variable **nominal polytomous qualitative variable** with the ranges before as its possible values.

- **Adequate antibiotic prophylaxis:**

This variable will be considered a **nominal dichotomous qualitative variable,** as its possibles values will be presence (yes) or absence (no) of this prevention action.

	Variable		Type of variable	Values or data
Covariables	ASA score		Nominal dichotomic qualitative	I-III / Above III
	Age			Below 65 years / Above 65years
	Sex			Male or female
	BMI		Nominal polytomous qualitative	Below 25 / 25-30 / Above 30
	Diabetes Mellitus		Nominal dichotomic qualitative	Yes/ no
	Immunosuppression		Nominal dichotomic qualitative	Yes/no
	Previous abdominal surgery			
	Previous abdominal radiotherapy			
	Albumin		Nominal polytomous qualitative	Below 30 / 30-35 / Above 35
	Adequate antibiotic prophylaxis		Nominal dichotomic qualitative	Yes/ no
	Renal failure	Creatinine (Cr)	Nominal dichotomic qualitative	0.6 - 1.3 mg/dL / above 1.3 mg/dL
		Urea	Nominal dichotomic qualitative	6 - 24 mg/dL / above 24 mg/dL
		eGFR (CKD-EPI)	Nominal polytomous qualitative	- >90 ml/min/1.73m^2 - 60-90 ml/min/1.73m^2 - 30-59 ml/min/1.73m^2 - <30 ml/min1.73m^2
	Reason for the elective colorectal surgery			- Neoplasia - IBD - Others

Table 6. Variables and measurement (II). Covariables: type and values. Own elaboration.

7.6 Study intervention:

7.6.1 Enrolment:

To be included in the study it is necessary to have developed an organ-space surgical site infection in the 30 days after an elective colorectal surgery. (*see "Study population", "Inclusion and exclusion criteria" and "Sample selection").*

7.6.2 Creation of the two groups:

As soon as the surgical site infection is diagnosed, a clinical assessment and surgical evaluation will be made for each case to decide which approach will be preferable: reintervention or the percutaneous radio-guided drain placement, considering the patients comorbidities and clinical history.

Thus, the ones who will decide in which group of intervention the patient is assigned to will be the radiologists from the interventionism team and the surgeons from the surgical team. We assume the groups we will obtain will be non-equivalent.

From this point onwards, the intervention will be initiated.

7.6.3 Intervention:

Depending on the group the patient is assigned to, we will differentiate between:

- **Radio guided drain placement** (32)**:**

This minimally invasive procedure to treat collections must be done in a radio-guided interventionism space, with CT or ultrasound availability.

The procedure of the radio-guided drain placement depends in great measure of the CT and other relevant imaging done previously to the intervention, as to determine the shortest possible route to drain the collection without damaging important structures.

The technique may be single step or multistep, but essentially consists in the placement of a two- or three-part access needle in the abscess/collection, followed by a stiff wire and serial dilators before placing a catheter attached to a vacuum drainage system (if the collections are peritoneal or retroperitoneal located) or an external drainage bag (for draining digestive tracts).

- **Surgical reintervention:**

The procedure of a colorectal reintervention will consist in the opening and debridement of the wound with drainage of the collection of liquid or pus inside the cavity (either via laparoscopic or open surgery).

7.6.4 Blinding:

As it is a quasi-experimental study, the main investigator as well as the surgical and radiologists' team will know in which intervention group the participant will be assigned to. The patient will also know the type of intervention he will receive, as he must receive the correct and accurate explanation of the procedure we will perform. It would be unethical not to do so. So, our study will be open-label or unblinded.

7.6.5 Follow up:

In both procedures, patients will be monitored regarding: pulse, blood pressure, SpO2, cardiac frequency and respiratory frequency. Moreover, the entry site will be reviewed on a daily basis, with adequate wound care.

The repeat of imaging should be considered after the intervention to evaluate the evolution of the collections.

The patient will be followed 3 months since the patient's discharge. While admitted in the hospital we will take daily blood samples until the parameters suggestive of active infection negativize. This way we can collect and obtain the data referring to the LOS and the duration of the infection for each case.

Once discharged, the patient will still be followed by a telephonic visit every month to check if there has been any need of consultation to the hospital in that time (assuming that each visit will also be recorded in the clinical history of each patient).

That way we can obtain the other variables: re-admission and mortality rates.

7.7 Data collection:

This project is a multicentric quasi-experimental study, meaning that participants will come from different public hospitals in Catalonia.

All participants must meet all the inclusion criteria and none of the exclusion criteria, and all data will be obtained through the clinical history. It will provide all information of the morbidities of each participant (presence or absence of systemic diseases, BMI, age, etc). Apart from the patient's medical comorbidities, it includes:

- Background of an elective colorectal surgery and the reason why it was performed.
- Background of previous abdominal surgeries and abdominal radiotherapy
- State of immunosuppression
- Renal function (estimated via previous blood tests performed).

All this information will also be checked in the first visit the clinician will do to each patient, with a directed anamnesis.

Before the intervention, we will elaborate a database that includes all the anterior variables and identify each patient with a random numeric code to maintain the anonymity and the confidentiality of all data collected. To guarantee a correct data collection we can hire a data quality control service.

7.7.1 First visit:

Once the patient has been diagnosed of an OS-SSI and we have checked the inclusion and exclusion criteria, we will check the clinical history and perform a directed anamnesis to collect all information related to all the covariables we will consider (*See Table 6."Variables and Measurement (II): Covariables").*

Sex and age of the patient	BMI
Medical history and comorbidities	History of abdominal surgeries
Immunosuppression	History of abdominal radiotherapy
Inclusion criteria	Exclusion criteria

Table 7. Initial data of the patient. Own elaboration.

Before the intervention, as a blood test must be obtained to determine the coagulation status, we will add a determination of albumin, to assess the nutritional status of the patient before obtaining control the focus of infection.

7.7.2 Follow-up:

After the intervention, blood tests will be performed daily to assess the evolution of inflammatory markers (as specified in the dependent variables we will focus on CPR, procalcitonin and white blood cell count), and monitorization of blood pressure, temperature, basal oxygen saturation, cardiac frequency, and respiratory frequency as well as the presence of fever.

All this data will be updated automatically in the clinical history and on our database after each determination to facilitate the later analysis.

7.8 Safety

The quasi-experimental study design will ensure that each patient is assigned to the intervention group that can best resolve the SSI, as to guarantee the safest approach for each patient. If after the intervention, some complication arises and there is clinical worsening meaning the control of the focus of infection is not achieved, there is the possibility of having to endure an exploratory laparoscopy (reintervention), in both groups of patients. That will be considered during the data analysis.

The percentage of patients that will not obtain control of infection with the first intervention are included in the 10% loss considered previously when calculating our study sample size, as it will complicate the obtention of data and may bias the conclusions extracted from the data analysis if included in the sample.

7.9 Flow-chart

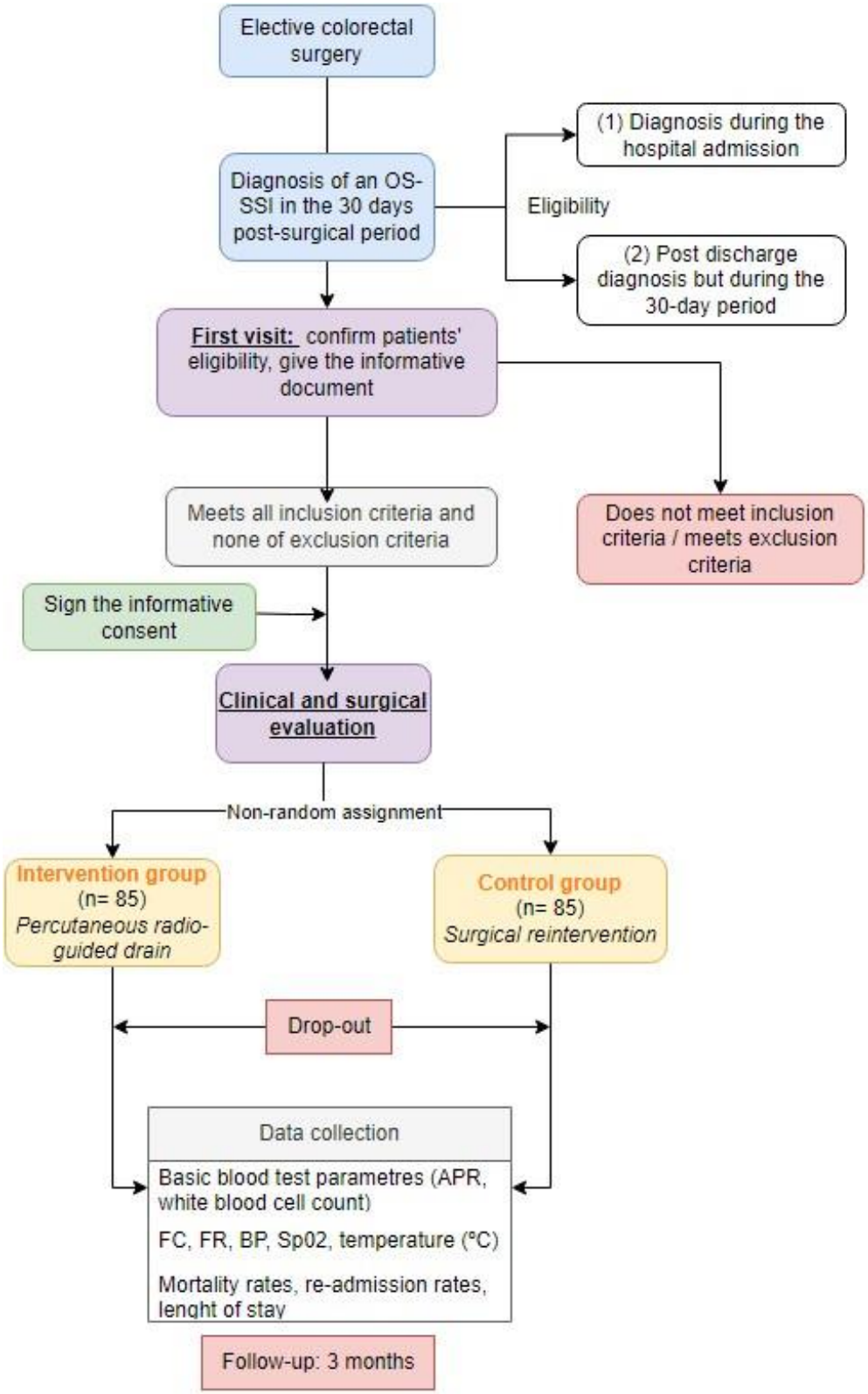

Figure 4. Flow-chart of the project. Own elaboration.

8. STATYSTICAL ANALYSIS:

The analysis of the data collected will be done by a statistical analyst, who will do the investigation blinding to ensure he/she is not biased by any group, and it will not interfere with the result.

The software used will be "*Statistical Package for Social Sciences or SPSS*" software version 28.1. A p-value of <0.05 will be considered statistically significant, defining a 95% confidence interval (CI) for all the analysis we will apply.

8.1 Descriptive analysis:

In both groups (percutaneous radio-guided drainage placement or reintervention group) the statistics will summarise the quantitative variable (*mortality rates, re-admission rates, duration of the infection and length of stay*) by using **means, standard deviation, medians, and interquartile range (IQR).**

These descriptives will be stratified between intervention and control group and additionally stratified by the covariables.

8.2 Bivariate analysis:

Student's T test will be the type of analysis used to evaluate if there are differences depending on the quantitative variables (*means of mortality rates, length of stay, re-admission rates and duration of the infection*).

8.3 Multivariate analysis:

It is necessary to do a multivariate analysis as to adjust the independent variable and dependent variables according to the covariables, as to avoid any possible confusion, since they can interfere in the results.

A linear regression model will be used for the association of the intervention with the **quantitative variables** (*mortality rates, length of stay, re-admission rates and duration of the infection).*

9. ETHICAL AND LEGAL CONSIDERATIONS:

9.1 Ethical principles:

This study will be performed under the considerations and requirements of the "***Declaration of Helsinki of Ethical Principles for Medical Research Involving Human Subjects***" established by the World Medical Association (WMA) and last reviewed in October 2013 (33).

This quasi-experimental study also obeys the ***"Principals of Biomedical Ethics from Beauchamp and Childress"***, also known as the "*Four fundamental Ethical principles"* as described below.

Our project is considered a low intervention study: we compare two approaches already authorised, indicated, and used to treat the pathology we include in the study, or in other words, the study follows the terms of marketing authorisation, published scientific evidence on safety and efficacy (34), so it will not be required to pay for an insurance. Additionally, as it is a study without commercial purpose, it will also not be required to pay the study taxes.

- Beneficence:

This ethical principle stands for the moral obligation to act in benefit for others. It reflects the higher positive outcome of the generated knowledge compared to the negative outcomes and risks that the project can involve.

In this study the principle is fulfilled because both approaches are indicated and have proved to be beneficial in the resolution of collections or infections with evidence-based studies, with good safety profiles.

The intervention group assignment will be done according to the surgical and radiologists' teams' evaluation, as to give each patient the best treatment within their circumstances (in case a collection cannot be accessed safely via percutaneous radio-guided approach for example, it will be assigned to the control group and not to the intervention group as to give them the best prognosis).

We expect better outcomes in the intervention group (radio-guided drain placement) as in mortality, re-admission rates and duration of infection but we made the design of the study a quasi-experimental design as to do no harm to any participant using the randomization as the assignment tool to each group of intervention; even though the study design that gathers the best evidence in the comparison of interventions is a randomized clinical trial.

The conclusion of this study can result in the elaboration of surgical profiles to assure the best treatment option for each patient, considering all the comorbidities and relevant data of the clinical history of each case. This could help the creation of further protocols and achieve better optimization of the resolution of the organ-space surgical site infection.

- Non-maleficence:

Both approaches to gain control of the focus of infection have been proven useful and have not demonstrated any type of detrimental effects on the outcome of the patients.

There are complications associated with both interventions, but to assure that no malicious intent is being done to the study participants, the surgical and radiologists' teams will do a thorough evaluation of each patient before assigning them in one of the intervention groups.

- Justice:

There will be equal distribution of health resources in the study. All participants who meet the totality of the inclusion criteria and none of the exclusion criteria admitted or treated in any of the hospitals participating int this study will have the same possibility to enter the project.

Every one of the patients will be given the same information and will have the same possibility to receive one intervention approach or another, depending only on the clinical assessment of their comorbidities and all the covariables explained before.

No participant will be discriminated for their ethnicity, socioeconomic status or any other aspect.

- Autonomy:

Reflects the capability of each participant to make choices regarding their own health, based on their values and preferences.

To assure this principle is respected we will give an informative document about the study protocol (*See Annex 16.3 and 16.4)* in the language preferred by the patient, to provide all information and knowledge necessary to understand the aim of the study and to decide if they want to participate in it.

A written informative consent (*See annex 16.5 and 16.6)* will be obtained from each participant before the participation of the study, in the first visit with the research team.

As the procedure to treat the surgical site infection is quite pressing, the obtention of the informative consent should be done during this first visit, once the patient has had the opportunity to ask all doubts and uncertainty.

It is mandatory to assure the patient understands the risks entailed in the project, the process of the intervention and all data the research team will collect. Apart from that, we must remember the participants their participation is totally voluntary and can withdraw from the project any time they want to, without any type of penalty.

In consequence, according to the "***Ley 41/2002 del 14 de noviembre, básica reguladora de la autonomía del paciente y de Derechos y Obligaciones en materia de Información y Documentación Clínica"*** the decision whether to participate or not to in the study will be respected (35).

The project will be submitted to the clinical investigation ethical committee or CEIC of each participant hospital and their suggestions will be considered as to improve the protocol, as its approval is mandatory to start the study.

9.2 Privacy and confidentiality:

The confidentiality and privacy of the patient is guaranteed through the "***Ley Orgánica 3/2018 del 5 de diciembre, de Protección de Datos Personales y garantía de los Derechos Digitales"*** (36) and "***Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data"*** (37)***.***

All the data collected from the participants will be anonymous, via generating a random numeric code for each patient once the database is created, as to confidentially analyse it. All data collected will only be available for the investigator and its research team, and exclusively used for the aim of the study and the research.

9.3 Transparency:

The investigators of this study declare the absence of conflicts of interest. The main goal of the study is to gather evidence and develop knowledge as to improve the quality of healthcare by optimizing a treatment approach.

All the investigators agree to publish all data and results with total transparency despite the results obtained, including unfavourable data or events.

10. WORK PLAN AND CHRONOGRAM:

10.1 Participating centres:

The participating centres will be selected and decided from the totality of public hospitals of Catalonia once they have been explained the protocol and objectives of the study and they have given their approval to enrol in our study.

10.2 Research team members:

The necessary personnel and research team to make this study possible, include:

- **Main investigator (MI) and general coordinator:** the person leading the study, who will be in contact with the coordinators of each hospital participating in the study and organize the study setting goes according to plan.

The principal centre of the study will be Hospital Josep Trueta, and the main investigator with their research team will coordinate the rest of the centres.

- **Hospitals coordinators (HC):** clinical coordinators we will place in each centre participating to coordinate the data collection and ensure the correct application of the protocol in each centre. They will be in constant contact with the MI.

As it will be a multicentric study, HC will be assigned in each centre participating, and will receive feedback from surgeons and radiologists of each hospital (included in the HCP category). They will meet with the main investigator every two months by videoconference to check if the study is proceeding without incidences.

The main investigator of the study in the HUJT will also be in charge of assigning secondary researchers if there's need to, and also to communicate with the analyst that later will be in charge of analysing the data.

- **Healthcare professionals (HCP):** the surgical teams and radiologists that will oversee doing the interventions.

Not only we will count on the surgical team and radiologist interventionism team, but also the anaesthesiology team, nurses, assistants, and internal medicine team.

Meeting must be done monthly to update the HC, to report back as much information as possible to the MI in their reunions, as to also update the database.

The elaboration, discussion, and conclusion of the results of the study will be exposed and written by the MI with the help of the HC, the secondary researchers, the analyst, and the HCP.

- **Statistical analyser:** a person that will carry out the statistics based on the database we will elaborate. All results obtained from the statistical analysis will be given to the MI and the research team as to extract conclusions and proceed to the paper redaction.

10.3 Study stages:

The totality of the study will have an estimated duration of 26 months or two years and two months. The steps done on this quasi-experimental will follow the diagram below, grouped in stages.

STAGE 0: Study design → *September 2023 to November 2023*

The beginning of the project. In this period of time, we will do all the bibliographic research from which we will base our study on and elaborate the protocol of our study.

The MI will get the help from the HC and HCP from each centre to develop the idea or problem they want to resolve and develop the protocol, making sure its capability of being reproduced and applied in each centre correctly and thoroughly.

- **First meeting** (*September 2023)*

The development of the project was accorded by Dra. Carol Batlle (Co-investigator) and Elena Rubió (principal investigator).

In this first meeting, a problem to solve is identified and an idea is generated. From this point forward the protocol will be elaborated.

- **Protocol design** (*September 2023-November 2023)*

In this part of the study design is where the literature review research will be done, and the hypothesis, objectives and methodology will be established. The research team will be the main responsible of this process.

- **Decision of which hospitals will participate in the study** (*September 2023-November 2023)*

The research team will contact the hospitals to explain the protocol and ask for their participation in the study. All hospitals that agree to the enrolment will receive a copy of the protocol and will select a clinical coordinator (HC). The research team will be the main responsible of this process.

STAGE 1: Ethical evaluation and approval → (*November 2023 to January 2024)*

The approval of the Ethics Committee of Clinical Investigation (CEIC) is mandatory to start the study.

- **Presentation of the protocol to the CEIC of each hospital (***November 2023)*

After the presentation of the protocol, any necessary modification or consideration that the CEIC recommends will be applied to it as to achieve the CEIC conditions for approval.

- **Approval of the protocol for the CEIC of each hospital (***January 2024)*

STAGE 2: Initial coordination → (*January 2024)*

- **Informative meeting:**

In this part of the process, the research team will meet with the clinical hospitals coordinators (HC) of each hospital at the Hospital Josep Trueta to carefully explain the protocol, its objectives, and the hypothesis we want to confirm.

We will also distribute tasks and organise the forthcoming process, elaborating the chronogram and explaining all the methods we will use for data collection.

The main investigator, hospital coordinators and healthcare professionals will meet every 2 months by videoconference to ensure the protocol is being followed properly.

- **Database creation:**

The database in which all data from the patients that meet all inclusion criteria and none of the exclusion criteria will be added. Each patient will be encoded by a random numeric code as to anonymize and preserve confidentiality.

- **Formation sessions:**

As the surgical team and interventionist radiologists' team is already trained to perform each intervention and have a lot of experience in this area, the formation sessions will be focused on the collection and registration of data in the database.

This will ensure a correct data collection to obtain representative conclusions in the final steps of the study.

STAGE 3: Recruitment and data collection → (*January 2024- September 2025)*

- **Sample recruitment:** (*January 2024- June 2025)*

We will use a non-probabilistic consecutive sampling, to obtain the totality of 170 patients needed in the study. Patients will be included in the study if they check all the inclusion criteria and none of the exclusion criteria, and most importantly, if they sign the informative consent of participation.

The patient's recruitment is approximately calculated to last a year and a half, but we have added an extra period of three months to give enough time to do a follow-up to the patients included in the study in the last months of the obtention of the sample.

In case of achieving enough patients for our sample before the period is finished, we will continue collecting the data to increase the statistical power of the study.

This process will be carried out by the research team and the hospitals' coordinators in each centre.

- **Intervention and follow-up visits:** (*January 2024- September 2025)*

The patients enrolled in the study will be assigned either on the intervention group or either in the control group by a non-randomized method, depending on the surgical and radiologists' team medical opinion.

Afterwards, the patient of each group will be followed for three months. In the period the patient is still hospitalized, a daily blood test will be performed to evaluate the APR parameters and intensely monitored to register blood pressure, cardiac frequency, respiratory frequency, temperature and Sp02.

After discharge, a two-weekly telephonic visit will be agreed to as to follow the clinical situation of each patient and ask for any major complication or hospital admission.

- **Data collection:** (*January 2024- September 2025)*

The data will be registered in the database as well as the patients' medical history, by the physicians in charge of each patient, and transferred to the hospital coordinators of each hospital to include in the database.

The main investigator, hospital coordinators and healthcare professionals will meet every 2 months by videoconference to ensure the protocol is being followed properly. At this point, if there is some kind of error or action that is not working, fixing actions will need to be taken.

STAGE 4: Statistical analysis → (*September 2025-November 2025)*

- **Statistical analysis of the data collected:** (*September 2025- October 2025)*

The statistical expert we hired will perform the statistical analysis, approximately during a one-month period. Finally, the results will be sent to the MI and the totality of the research team to interpret, discuss, and proceed to the paper redaction.

- **Interpretation of the results:** (*October 2025- November 2025)*

The research team will interpret and discuss the results and extract conclusions from them for each participating hospital. Then the discussion and edition of the paper may be elaborated.

STAGE 5: Conclusion, discussion, and publication → (*November 2025- December 2025)*

- **Paper redaction:**

The research team is in charge of writing down all conclusions extracted from the data collected, and write an article with all information, accurately explained, of the process as to not only display and publish the results and conclusions but also to make the study reproducible.

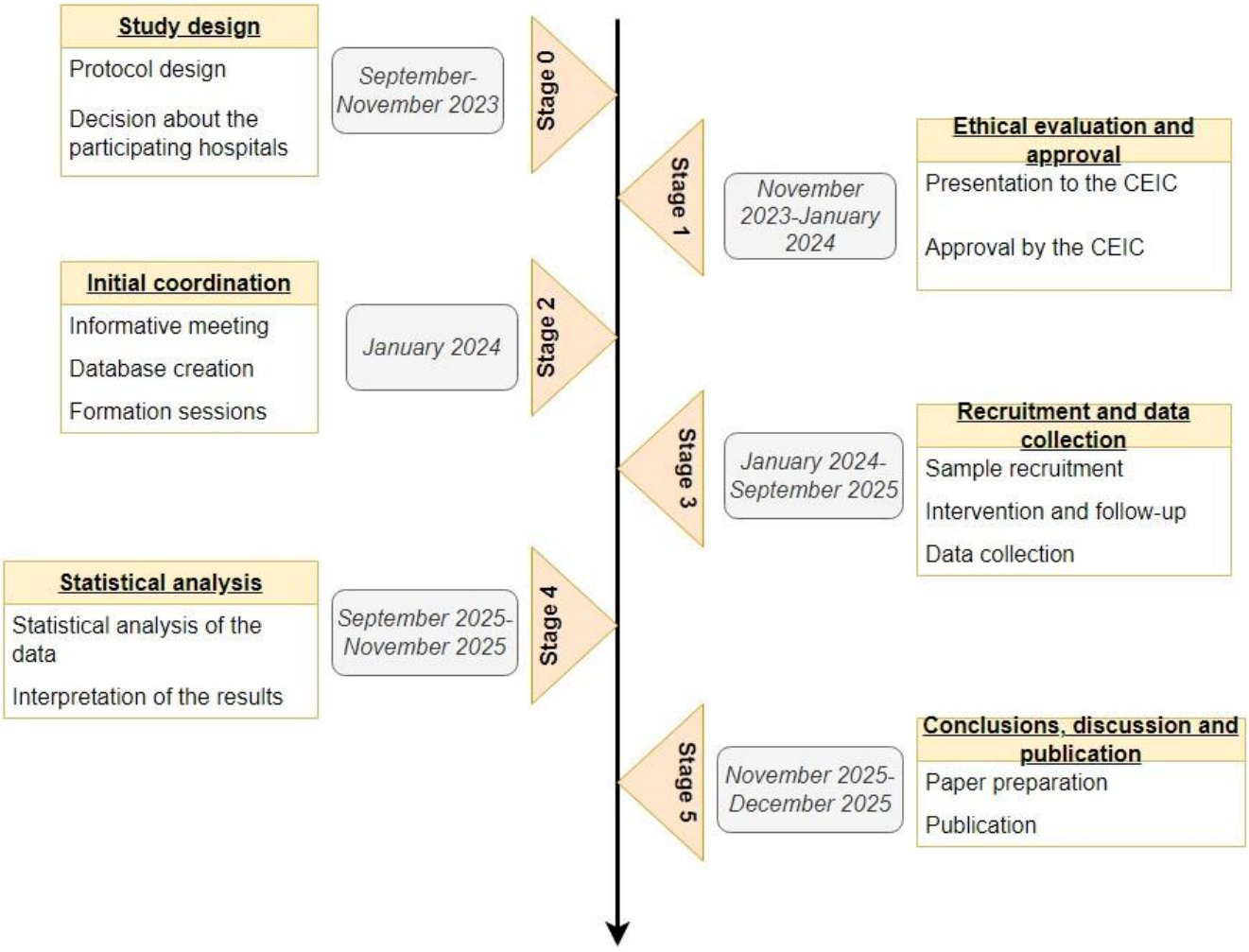

***Figure 5.** Study stages. Own elaboration.*

ACTIVITIES	2023				2024																							
	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
STAGE 0: STUDY DESIGN																												
First meeting																												
Protocol design																												
Decide the hospitals participating																												
STAGE 1: ETHICAL AVALUATION AND APPROVAL																												
Presentation and approval by CEIC																												
STAGE 2: PREPARATION AND COORDINATION																												
Informative meeting																												
Database creation																												
Formation sessions																												
STAGE 3: RECRUITMENT AND DATA COLLECTION																												
Sample recruitment																												
Intervention and follow-up																												
Data collection																												
STAGE 4: STATISTICAL ANALYSIS																												
Statistical analysis of the data																												
Interpretation of the results																												
STAGE 5: DISCUSSION, CONCLUSIONS																												
Paper preparation and redaction																												
Publication																												

Figure 6. Chronogram of the project. Own elaboration.

11. BUDGET PLAN:

11.1 Not included costs:

The personnel of each hospital participating in the study and included in the research team will not receive any economical compensation or reward for the study's reason. All the people who will attend the patients and operate on the participants are part of the public National Health System. The motivation to involve themselves in the project will be the evidence it will help gather and the further impact of the study in health and in the optimization of the SSI's treatment.

The hospitals participating in the study already have the tools and spaces to perform both approaches, and also have the resources (as we've stated in "*Study Setting"*) for further treatment if help from other specialties is needed in case of an emergency (such as ICU). Thus, the material will not be considered in the study budget.

We will use the SPSS database license provided by the IDIBGI, therefore there will be no need to pay for the database license.

Our project consists of a low intervention study, as we compare two approaches already authorised, indicated, and used to treat the pathology we include in the study *(See "Ethical and legal considerations").* Therefore, there will be no need for an insurance, neither study taxes (since there is no commercial purpose either).

11.2 Included costs:

- Personal costs:
    - Statistical analysis: we will need to hire a statistician or statistical analysis service to analyse all the data collected. The approximately wage of a statistician is 35€/hour for approximately 150h of work.
- Material costs:
    - Printing costs: informative document (4 pages), informed consent (2 pages), are required to print for each participant (in the language preferred).

The printing cost is 0.03€/page for the total of 6 pages per patient.

The sample needed for the study is formed by a total of 170 patients, however, it is possible that more information documents may need to be printed.

- Divulgation costs:
    - Publication fees: after writing down the journal and extract conclusions from the data collected and the analysis performed, it is expected to publish the article with the results obtained. We assume a total of 2.000€ for publication fees.
    - Linguistic correction: proofreading the journal article will be necessary before publishing it, to avoid errors. The budget assumed for this purpose is approximately 250€.
    - National and international congress: if the study is presented by the MI to a congress, we should calculate a part of the budget destined to the inscription (700 and 2500€ for each of them respectively).

	Type of cost	Unit cost	Hours or units	SUBTOTAL
Subcontracted services	**Statistical analysis**	35€/h	150 h	5250€
				Subtotal: 5250€
Material costs	**Printing costs**	0.03€/page	6 pages for 124 patients	22,32€
				Subtotal: 22,32€
Divulgation costs	**Article publication fees**	2000€/publication	1	2000€
	Linguistic correction	250€/article	1	250€
	National congress	700€/attendant	1	700€
	International congress	2500€/attendant	1	2500€
				Subtotal: 5450€
			TOTAL COST	10.722,32€

Figure 6. Total and detailed budget of the study. Own elaboration.

12. LIMITATIONS AND STRENGHTS:

- **Limitations:**

The greatest disadvantage of the study is its quasi-experimental design. As the participants are not assigned by randomization to each group of intervention, we are assuming both groups will not be homogeneous, affecting to the ability of the study to extract conclusions and causal associations between intervention and outcome.

The method of sampling will also be subjected to some bias, as a non-probabilistic consecutive method will be applied. It contributes to the possibility of recruiting a sample of participants that may not resemble the reality of the population and the obtention of unrepresentative results.

So, the design of the study will be influenced by the fact that the groups will be non-equivalent and there might be some selection bias. However, the multivariate analysis and the adjustment for potential confounders (covariables) will increase the internal validity of the study.

As the study is also multicentric, there may be some variability between the results of each hospital, depending on the work of each medical service. The interventions may be subjected to some operator-dependent variability, but the constant communication between HCP, HC with the MI and the rest of the research team and also the standardization of the protocol will minimise the variability and homogenise the results.

Even though a quasi-experimental study design was needed to ensure the principal of beneficence was respected, and ensure that each patient gets the best possible approach to treat their OS-SSI, this non-randomized assignment tool based on a clinical and surgical evaluation may lead us to **overestimate** the rates of complication and mortality in the control group (surgical reintervention), as the patients with worse prognosis will probably be assigned to this group (as an exploratory laparoscopic may be the best approach to detect accurately the focus and extension of the pathology underneath).

- **Strengths:**

We chose a quasi-experimental study design as its degree of evidence is higher than an observational study or prospective cohorts' study. Even though the most accurate study design to compare both interventions would be a clinical trial, it wouldn't be ethical to decide randomly which intervention group we assign each participant to, without taking into account if the patient would really benefit from it or not.

The study also has an achievable budget considering the future benefits that can be obtained with the evidence gathered.

13. CLINICAL AND HEALTHCARE IMPACT:

As we've stated, surgical site infections are still a relevant, multifactorial and ongoing challenge with great impact in healthcare, all around the world, due to its mortality rates, increased length of stay (that can also be a risk factor for a lot of hospital related complications) and re-admission rates.

As of right now, the decision on how to treat an organ-space surgical site infection relies on the surgical and clinical evaluation. Our study aims to collect data to not only state which of the interventions is best to treat the surgical site infections (according to the mortality rates, length of stay, re-admission rates and the duration of the infection) but also to correlate this data conclusions to the context of each patient (comorbidities, history of abdominal surgeries or radiotherapy, immunosuppression, etc) to make a step into the elaboration of surgical profiles that can achieve a better optimization of the OS-SSI treatment, decreasing all this impact that these types of surgical site infections have still in our healthcare systems.

14. FEASABILITY:

It is a multicentric quasi-experimental study, that will be carried in some hospitals in Catalonia, all of them with disposal of tools and spaces to perform both interventions considered in the study and clinical teams with experience in the area.

With the participation of all this centres, and according to the annual data recollection of VINCAT of the total of OS-SSI developed, it is feasible to achieve the required sample size (170 patients) in a year and a half.

Participants are not expected to be reluctant to enter the study, as the decision of which group of intervention will be decided together by the surgical and radiologists' teams according to their characteristics and with the intent of obtaining the maximum benefit and prognosis for each case. It also helps the fact that both approaches are already approved to treat surgical-site-infections, and used to treat them on the daily practice, therefore, we are not exposing the participants to any additional risk.

The budget of the study is feasible, considering again that all hospitals will already have the material, tools, and expert teams to perform the interventions, and only the statistician will be hired as additional personnel.

In conclusion, it is feasible to proceed with the study.

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16. ANNEXES:

16.1 ANNEX 1. VINCat annual report (2022). Surveillance of SSI (10)

- **Colon surgery:**

Codi UP - Nom UP	Nombre d'intervencions
Grup I: Hospitals de més de 500 llits (9 centres)	
00100 - Hospital U de Girona Doctor Josep Trueta	67
00148 - Hospital Universitari de Bellvitge	70
00272 - H. U. Germans Trias i Pujol de Badalona	112
00718 - Hospital Clínic de Barcelona	100
00729 - Hospital Universitari Mútua de Terrassa	89
00741 - Hospital de Sabadell	121
00746 - Hospital del Mar - H. de l'Esperança	99
00772 - Hospital de la Santa Creu i Sant Pau	160
06046 - Hospital Universitari Vall d'Hebron	121
Grup II: Hospitals d'entre 200 i 500 llits (17 centres)	
00001 - Hospital U. Arnau de Vilanova de Lleida	150
00039 - Hospital Univ. Joan XXIII de Tarragona	87
00086 - Hospital de Tortosa Verge de la Cinta	47
00634 - Althaia, Hospital de Sant Joan de Déu	97
00744 - Hospital de Terrassa	57
00745 - Hospital Universitari de Vic	50
00750 - Hospital General de Granollers	97
00763 - Hospital Universitari Sant Joan de Reus	74
* 00769 - Hospital Sant Rafael	8
00785 - Hospital Universitari Quirón Dexeus	38
00833 - Hospital Universitari Sagrat Cor	32
00916 - Hospital d'Igualada	33
01425 - Hospital de Mataró	79
01579 - Hospital General de Catalunya	42
03401 - Centro Médico Teknon, Grupo QuironSalud	82
03520 - Hospital de Barcelona	73
05994 - H. de l'Hospitalet-H. Moisès Broggi	132
Grup III: Hospitals de menys de 200 llits (26 centres)	
00146 - Hospital de Viladecans	61
00636 - Centre Mèdic Delfos	23
00668 - Clínica Girona	26
00724 - Hospital de Figueres	26
00734 - Fundació Hospital de l'Esperit Sant	41
* 00737 - Hospital Comarcal Móra d'Ebre	6
00739 - Hospital de Palamós	27
00742 - Parc Sanitari Sant Joan Déu - HG	48
00753 - Hospital Municipal de Badalona	38
00754 - Hospital Residència Sant Camil	63
00757 - Hospital Comarcal de Sant Bernabé	13
00759 - HC Sant Jaume Calella i HC de Blanes	50
00762 - Hosp. d'Olot i Comarcal de la Garrotxa	20
00764 - Hospital Sant Joan de Déu (Martorell)	44
00767 - Hospital Sant Pau i Santa Tecla	38
00770 - Hospital Santa Caterina	34
00826 - Pius Hospital de Valls	24
* 00834 - Clínica NovAliança	8
* 00836 - Clínica Terres de l'Ebre	2
00908 - Hospital de Mollet	74
01012 - Hospital Comarcal de l'Alt Penedès	41
03400 - Hospital QuirónSalud Barcelona	51
04199 - Hospital Sanitas Cima	12
04373 - Hospital del Vendrell	30
04392 - Hospital Montserrat	11
07758 - Àptima Centre Clínic - Terrassa	15

Figure 7. Hospitals that participate in colon surgery. Extracted from VINCat annual report (2022).

Característiques		Global			Grup I			Grup II			Grup III		
		N	%	% ILQ	N	%	% ILQ	N	%	% ILQ	N	%	% ILQ
Nº centres participants		48	-	-	9	-	-	16	-	-	23	-	-
Nº d'intervencions		2.919	-	-	939	-	-	1.170	-	-	810	-	-
Sexe	Dona	1.248	42,8	5,29	414	44,1	4,35	500	42,7	7,00	334	41,2	3,89
	Home	1.671	57,2	9,28	525	55,9	10,29	670	57,3	9,40	476	58,8	7,98
Edat	18 a 30 anys	21	0,7	0,00	12	1,3	0,00	6	0,5	0,00	3	0,4	0,00
	31 a 45 anys	115	3,9	7,83	45	4,8	6,67	44	3,8	11,36	26	3,2	3,85
	46 a 60 anys	464	15,9	7,97	130	13,8	8,46	199	17,0	9,05	135	16,7	5,93
	≥60	2.319	79,4	7,55	752	80,1	7,71	921	78,7	8,14	646	79,8	6,50
Duració IQ > P75	No	1.549	53,1	5,29	392	41,7	4,34	716	61,2	6,56	441	54,4	4,08
	Sí	1.370	46,9	10,15	547	58,3	10,05	454	38,8	11,23	369	45,6	8,94
NISS:	-1,0	2.027	69,4	5,13	599	63,8	4,84	872	74,5	5,85	556	68,6	4,32
	1	748	25,6	11,50	281	29,9	10,68	257	22,0	12,84	210	25,9	10,95
	≥2	144	4,9	21,53	59	6,3	22,03	41	3,5	34,15	44	5,4	9,09
Profilaxis ATB	Inadequada	472	16,3	10,38	76	8,1	14,47	257	22,0	10,89	139	17,4	7,19
	Adequada	2.432	83,7	7,03	861	91,9	7,08	912	78,0	7,57	659	82,6	6,22
Cirurgia endoscòpica	Sí	2.357	81,3	6,07	750	80,3	5,73	968	82,9	6,51	639	80,2	5,79
	No	541	18,7	14,42	184	19,7	15,76	199	17,1	17,59	158	19,8	8,86
Infeccions de Localització Quirúrgica (ILQ):													
ILQ		**221**	**-**	**7,57**	**72**	**-**	**7,67**	**98**	**-**	**8,38**	**51**	**-**	**6,30**
Percentils:	25%			3,15			5,97			6,26			2,02
	75%			9,50			9,09			10,05			9,81
Tipus ILQ	Superficial	51	23,1	1,75	16	22,2	1,70	23	23,5	1,97	12	23,5	1,48
	Profunda	18	8,1	0,62	4	5,6	0,43	7	7,1	0,60	7	13,7	0,86
	Òrgan-Espai	152	68,8	5,21	52	72,2	5,54	68	69,4	5,81	32	62,7	3,95
Detecció ILQ	Ingrés	146	66,4	5,00	49	69,0	5,22	63	64,3	5,38	34	66,7	4,20
	Post-alta	32	14,5	1,10	13	18,3	1,38	14	14,3	1,20	5	9,8	0,62
	Reingrés	42	19,1	1,44	9	12,7	0,96	21	21,4	1,79	12	23,5	1,48

Figure 8. Number and percentage of interventions and colon surgical-site-infections, according to different characteristics. Extracted from VINCat annual record (2022).

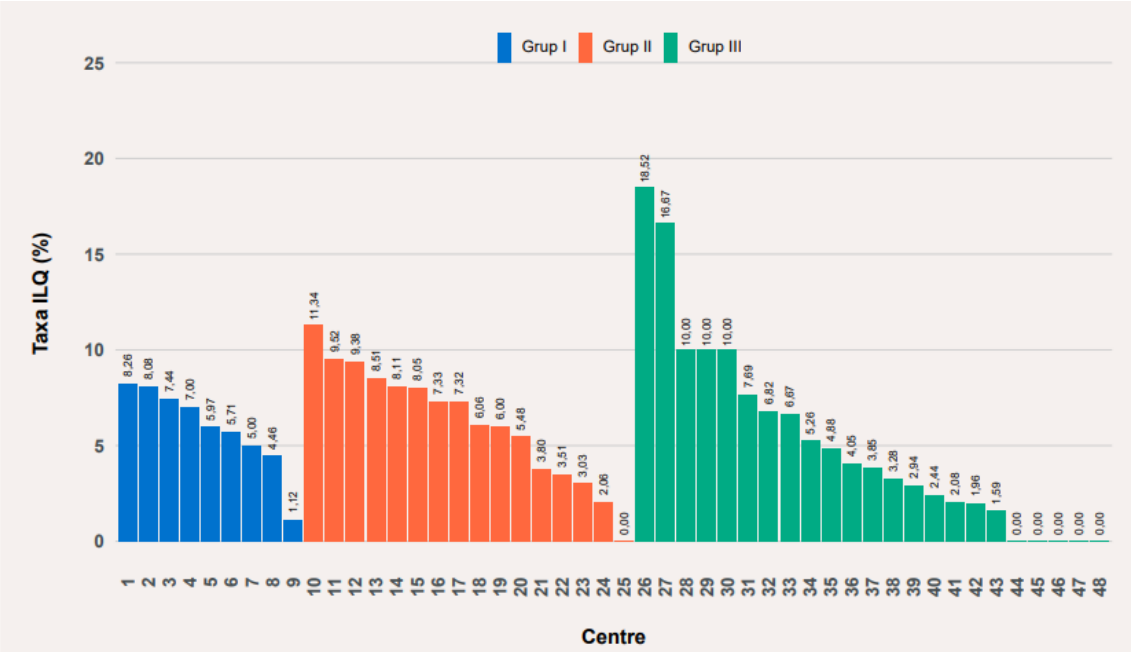

Figure 9. OS-SSI rates in colon surgery, classified by type of hospital. Extracted from VINCat annual record (2022).

Any	N IQ	ILQ superficial			ILQ profunda			ILQ d'òrgan i espai			ILQ global		
		N ILQ	% ILQ	[IC 95%]	N ILQ	% ILQ	[IC 95%]	N ILQ	% ILQ	[IC 95%]	N ILQ	% ILQ	[IC 95%]
2011	2.355	184	7,81	[6,80 a 8,97]	77	3,27	[2,62 a 4,07]	210	8,92	[7,83 a 10,14]	471	20,00	[18,43 a 21,66]
2012	2.416	159	6,58	[5,66 a 7,64]	64	2,65	[2,08 a 3,37]	203	8,40	[7,36 a 9,58]	427	17,67	[16,20 a 19,25]
2013	2.476	132	5,33	[4,51 a 6,29]	51	2,06	[1,57 a 2,70]	210	8,48	[7,45 a 9,65]	394	15,91	[14,52 a 17,41]
2014	2.535	167	6,59	[5,69 a 7,62]	60	2,37	[1,84 a 3,04]	189	7,46	[6,50 a 8,55]	416	16,41	[15,02 a 17,90]
2015	3.007	158	5,25	[4,51 a 6,11]	59	1,96	[1,52 a 2,52]	235	7,82	[6,91 a 8,83]	452	15,03	[13,80 a 16,35]
2016	3.400	133	3,91	[3,31 a 4,62]	46	1,35	[1,01 a 1,80]	213	6,26	[5,50 a 7,13]	392	11,53	[10,50 a 12,65]
2017	3.375	129	3,82	[3,23 a 4,52]	51	1,51	[1,15 a 1,98]	159	4,71	[4,05 a 5,48]	340	10,07	[9,10 a 11,14]
2018	3.268	94	2,88	[2,36 a 3,51]	25	0,76	[0,52 a 1,13]	167	5,11	[4,41 a 5,92]	287	8,78	[7,86 a 9,80]
2019	3.082	71	2,30	[1,83 a 2,90]	25	0,81	[0,55 a 1,20]	141	4,57	[3,89 a 5,37]	237	7,69	[6,80 a 8,68]
2020	2.513	42	1,67	[1,24 a 2,25]	18	0,72	[0,45 a 1,13]	111	4,42	[3,68 a 5,29]	172	6,84	[5,92 a 7,90]
2021	2.887	57	1,97	[1,53 a 2,55]	20	0,69	[0,45 a 1,07]	119	4,12	[3,45 a 4,91]	196	6,79	[5,93 a 7,77]
2022	2.919	51	1,75	[1,33 a 2,29]	18	0,62	[0,39 a 0,98]	152	5,21	[4,46 a 6,07]	221	7,57	[6,67 a 8,59]
TOTAL	**35.051**	**1.383**	**3,95**	**[3,75 a 4,15]**	**516**	**1,47**	**[1,35 a 1,60]**	**2.144**	**6,12**	**[5,87 a 6,37]**	**4.049**	**11,55**	**[11,22 a 11,89]**

Figure 10. Global SSI evolution and classified by type of infection. Extracted from VINCat annual record (2022).

- **Rectal surgery:**

Codi UP - Nom UP	Nombre d'intervencions
Grup I: Hospitals de més de 500 llits (9 centres)	
00100 - Hospital U de Girona Doctor Josep Trueta	72
00148 - Hospital Universitari de Bellvitge	48
00272 - H. U. Germans Trias i Pujol de Badalona	40
00718 - Hospital Clínic de Barcelona	76
00729 - Hospital Universitari Mútua de Terrassa	23
00741 - Hospital de Sabadell	40
00746 - Hospital del Mar - H. de l'Esperança	32
00772 - Hospital de la Santa Creu i Sant Pau	64
06046 - Hospital Universitari Vall d'Hebron	70
Grup II: Hospitals d'entre 200 i 500 llits (16 centres)	
00001 - Hospital U. Arnau de Vilanova de Lleida	69
00039 - Hospital Univ. Joan XXIII de Tarragona	44
00086 - Hospital de Tortosa Verge de la Cinta	14
00634 - Althaia, Hospital de Sant Joan de Déu	49
00744 - Hospital de Terrassa	18
00745 - Hospital Universitari de Vic	12
00750 - Hospital General de Granollers	34
00763 - Hospital Universitari Sant Joan de Reus	36
00785 - Hospital Universitari Quirón Dexeus	15
* 00833 - Hospital Universitari Sagrat Cor	7
00916 - Hospital d'Igualada	24
01425 - Hospital de Mataró	32
* 01579 - Hospital General de Catalunya	8
* 03401 - Centro Médico Teknon, Grupo QuironSalud	10
03520 - Hospital de Barcelona	13
05994 - H. de l'Hospitalet-H. Moisès Broggi	56
Grup III: Hospitals de menys de 200 llits (11 centres)	
* 00146 - Hospital de Viladecans	7
* 00636 - Centre Mèdic Delfos	5
00734 - Fundació Hospital de l'Esperit Sant	20
00753 - Hospital Municipal de Badalona	17
00759 - HC Sant Jaume Calella i HC de Blanes	20
00764 - Hospital Sant Joan de Déu (Martorell)	11
00767 - Hospital Sant Pau i Santa Tecla	20
00908 - Hospital de Mollet	23
03400 - Hospital QuirónSalud Barcelona	12
* 04199 - Hospital Sanitas Cima	2
* 07758 - Àptima Centre Clínic - Terrassa	2

Figure 11. Hospitals that participate in rectal surgery. Extracted from VINCat annual report (2022).

Característiques		Global			Grup I			Grup II			Grup III		
		N	%	% ILQ	N	%	% ILQ	N	%	% ILQ	N	%	% ILQ
Nº centres participants		30	-	-	9	-	-	14	-	-	7	-	-
Nº d'intervencions		1.014	-	-	465	-	-	426	-	-	123	-	-
Sexe	Dona	388	38,3	11,60	189	40,6	11,11	158	37,1	13,92	41	33,3	4,88
	Home	626	61,7	11,82	276	59,4	11,59	268	62,9	13,43	82	66,7	7,32
Edat	18 a 30 anys	3	0,3	0,00	3	0,6	0,00	0	0,0	-	0	0,0	-
	31 a 45 anys	34	3,4	11,76	10	2,2	10,00	18	4,2	16,67	6	4,9	0,00
	46 a 60 anys	206	20,3	11,65	89	19,1	11,24	94	22,1	13,83	23	18,7	4,35
	≥60	771	76,0	11,80	363	78,1	11,57	314	73,7	13,38	94	76,4	7,45
Duració IQ > P75	No	561	55,3	10,52	202	43,4	8,42	280	65,7	12,86	79	64,2	7,59
	Sí	453	44,7	13,25	263	56,6	13,69	146	34,3	15,07	44	35,8	4,55
NISS:	-1,0	727	71,7	9,77	300	64,5	7,33	336	78,9	12,50	91	74,0	7,69
	1	245	24,2	15,92	138	29,7	17,39	79	18,5	17,72	28	22,8	3,57
	≥2	42	4,1	21,43	27	5,8	25,93	11	2,6	18,18	4	3,3	0,00
Profilaxis ATB	Inadequada	157	15,5	16,56	36	7,8	16,67	86	20,2	22,09	35	28,5	2,86
	Adequada	854	84,5	10,89	426	92,2	11,03	340	79,8	11,47	88	71,5	7,95
Cirurgia endoscòpica	Sí	826	82,0	10,41	373	80,6	9,92	361	85,5	11,36	92	75,4	8,70
	No	181	18,0	17,68	90	19,4	17,78	61	14,5	26,23	30	24,6	0,00
Infeccions de Localització Quirúrgica (ILQ):													
ILQ		**119**	**-**	**11,74**	**53**	**-**	**11,40**	**58**	**-**	**13,62**	**8**	**-**	**6,50**
Percentils:	25%			5,64			2,50			7,85			2,50
	75%			15,63			14,29			16,49			7,29
Tipus ILQ	Superficial	20	16,8	1,97	5	9,4	1,08	12	20,7	2,82	3	37,5	2,44
	Profunda	20	16,8	1,97	9	17,0	1,94	11	19,0	2,58	0	0,0	0,00
	Òrgan-Espai	79	66,4	7,79	39	73,6	8,39	35	60,3	8,22	5	62,5	4,07
Detecció ILQ	Ingrés	74	62,2	7,30	30	56,6	6,45	41	70,7	9,62	3	37,5	2,44
	Post-alta	10	8,4	0,99	3	5,7	0,65	5	8,6	1,17	2	25,0	1,63
	Reingrés	35	29,4	3,45	20	37,7	4,30	12	20,7	2,82	3	37,5	2,44

Figure 12. Number and percentage of interventions and rectal surgical-site-infections, according to different groups of hospitals. Extracted from VINCat annual record (2022).

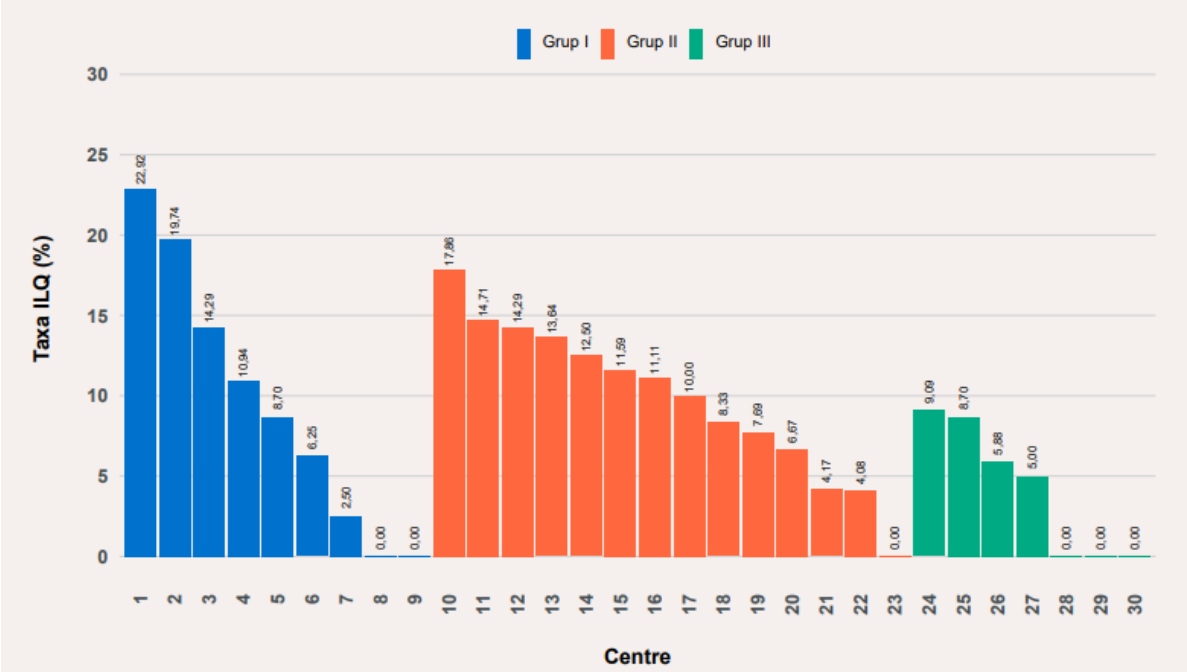

Figure 13. OS-SSI rates in rectal surgery, classified by type of hospital. Extracted from VINCat annual record (2022).

Any	N IQ	ILQ superficial			ILQ profunda			ILQ d'òrgan i espai			ILQ global		
		N ILQ	% ILQ	[IC 95%]	N ILQ	% ILQ	[IC 95%]	N ILQ	% ILQ	[IC 95%]	N ILQ	% ILQ	[IC 95%]
2011	1.000	65	6,50	[5,13 a 8,21]	56	5,60	[4,33 a 7,21]	105	10,50	[8,75 a 12,56]	226	22,60	[20,11 a 25,30]
2012	987	60	6,08	[4,75 a 7,75]	57	5,78	[4,48 a 7,42]	103	10,44	[8,68 a 12,50]	220	22,29	[19,80 a 25,00]
2013	1.050	54	5,14	[3,96 a 6,66]	42	4,00	[2,97 a 5,37]	122	11,62	[9,82 a 13,70]	218	20,76	[18,41 a 23,32]
2014	1.032	54	5,23	[4,03 a 6,77]	42	4,07	[3,02 a 5,46]	110	10,66	[8,92 a 12,69]	206	19,96	[17,63 a 22,51]
2015	1.105	55	4,98	[3,84 a 6,43]	44	3,98	[2,98 a 5,31]	128	11,58	[9,83 a 13,61]	227	20,54	[18,26 a 23,03]
2016	1.272	57	4,48	[3,47 a 5,77]	35	2,75	[1,98 a 3,81]	103	8,10	[6,72 a 9,73]	195	15,33	[13,45 a 17,42]
2017	1.234	50	4,05	[3,08 a 5,31]	30	2,43	[1,70 a 3,46]	104	8,43	[7,00 a 10,11]	184	14,91	[13,03 a 17,01]
2018	1.154	42	3,64	[2,70 a 4,89]	24	2,08	[1,40 a 3,08]	111	9,62	[8,05 a 11,46]	178	15,42	[13,45 a 17,63]
2019	1.066	35	3,28	[2,37 a 4,54]	17	1,59	[0,99 a 2,55]	73	6,85	[5,48 a 8,53]	125	11,73	[9,93 a 13,80]
2020	866	17	1,96	[1,22 a 3,14]	16	1,85	[1,13 a 3,00]	68	7,85	[6,24 a 9,84]	101	11,66	[9,69 a 13,98]
2021	976	17	1,74	[1,09 a 2,78]	17	1,74	[1,09 a 2,78]	99	10,14	[8,40 a 12,20]	133	13,63	[11,61 a 15,93]
2022	1.014	20	1,97	[1,28 a 3,04]	20	1,97	[1,28 a 3,04]	79	7,79	[6,29 a 9,61]	119	11,74	[9,89 a 13,87]
TOTAL	**12.934**	**530**	**4,10**	**[3,77 a 4,45]**	**401**	**3,10**	**[2,82 a 3,41]**	**1.217**	**9,41**	**[8,92 a 9,92]**	**2.149**	**16,62**	**[15,98 a 17,27]**

Figure 14. Global SSI evolution and classified by type of infection. Extracted from VINCat annual record (2022).

Figure 15. Responsible microorganisms for colon SSI. Extracted from VINCat annual record (2022).

COCS GRAM POSITIUS	**61**	**27,11**
Enterococcus faecium	25	11,11
Enterococcus faecalis	17	7,56
S. aureus sensible a la meticil·lina	6	2,67
S. aureus resistent a la meticil·lina (SARM)	2	0,89
S. coagulasa negatiu	2	0,89
Staphylococcus epidermidis	2	0,89
Streptococcus anginosus	2	0,89
Enterococcus spp.	1	0,44
S. lugdunensis	1	0,44
Staphylococcus spp.	1	0,44
Streptococcus mitis	1	0,44
Streptococcus agalactiae	1	0,44
BACILS GRAM NEGATIUS	**87**	**38,67**
Escherichia coli	37	16,44
Klebsiella pneumoniae	12	5,33
Pseudomonas aeruginosa	10	4,44
Enterobacter cloacae	6	2,67
Citrobacter freundii	3	1,33
Citrobacter spp.	3	1,33
Enterobacter aerogenes	3	1,33
Morganella morganii	3	1,33
Serratia marcescens	3	1,33
Klebsiella oxytoca	2	0,89
Klebsiella spp.	2	0,89
Aeromonas spp.	1	0,44
Proteus mirabilis	1	0,44
Proteus vulgaris	1	0,44
ANAEROBIS	**3**	**1,33**
Bacteroides grup fragilis	1	0,44
Bacteroides spp.	1	0,44
Clostridium spp.	1	0,44
FONGS	**11**	**4,89**
Candida albicans	9	4,00
Candida spp.	2	0,89
CULTIUS NEGATIUS	**6**	**2,67**
A.B. Cultius negatius	6	2,67
CULTIUS NO PRACTICATS	**51**	**22,67**
A.A. Cultius no practicats	51	22,67
IGUAL O MÉS DE 3 GÈRMENS	**4**	**1,78**
Igual o més de 3 gèrmens	4	1,78
ALTRES	**2**	**0,89**
Altres	2	0,89
TOTAL	**225**	

Figure 16. Responsible microorganisms for rectal SSI. Extracted from VINCat annual record (2022).

BACILS GRAM POSITIUS	**1**	**0,74**
Lactobacillus spp.	1	0,74
COCS GRAM POSITIUS	**38**	**27,94**
Enterococcus faecalis	14	10,29
Enterococcus faecium	13	9,56
S. aureus sensible a la meticil·lina	4	2,94
Streptococcus anginosus	3	2,21
S. pyogenes (grup A)	2	1,47
Enterococcus spp.	1	0,74
S. coagulasa negatiu	1	0,74
BACILS GRAM NEGATIUS	**50**	**36,76**
Escherichia coli	21	15,44
Pseudomonas aeruginosa	10	7,35
Klebsiella pneumoniae	7	5,15
Proteus mirabilis	4	2,94
Enterobacter cloacae	3	2,21
Morganella morganii	2	1,47
Klebsiella oxytoca	1	0,74
Klebsiella spp.	1	0,74
Pseudomonas spp.	1	0,74
ANAEROBIS	**2**	**1,47**
Bacteroides grup fragilis	1	0,74
Bacteroides spp.	1	0,74
FONGS	**7**	**5,15**
Candida albicans	5	3,68
Candida spp.	2	1,47
CULTIUS NEGATIUS	**2**	**1,47**
A.B. Cultius negatius	2	1,47
CULTIUS NO PRACTICATS	**24**	**17,65**
A.A. Cultius no practicats	24	17,65
IGUAL O MÉS DE 3 GÈRMENS	**3**	**2.21**
Igual o més de 3 gèrmens	3	2,21
ALTRES	**9**	**6,62**
Altres	8	5,88
Propionibacterium spp.	1	0,74
TOTAL	**136**	

16.2 ANNEX 2. "Do the right thing at the right time to stop surgical site infections" (28)

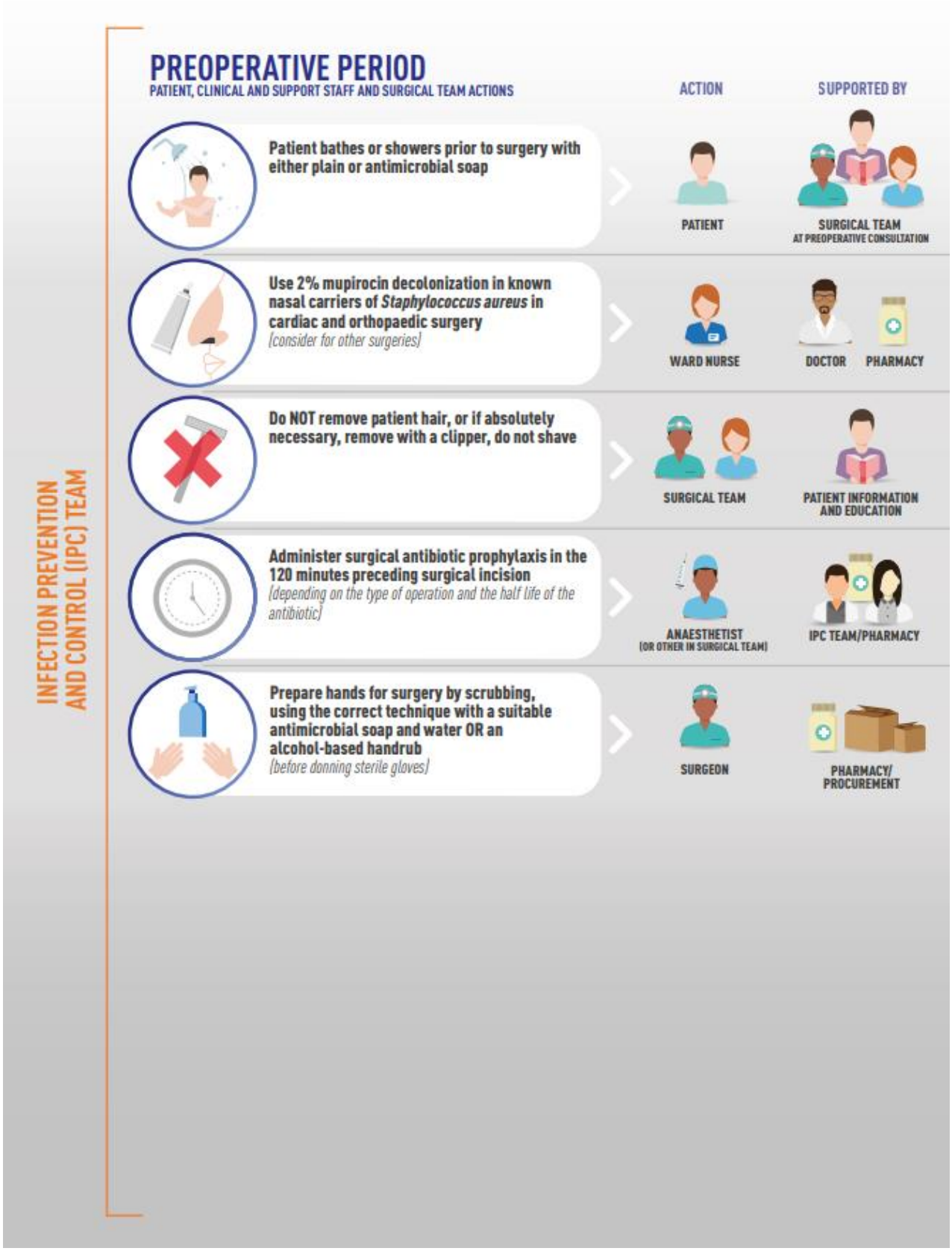

Figure 17. SSI prevention recommendations in the preoperative period (I). Extracted from the WHO web: "Do the right thing and the right time".

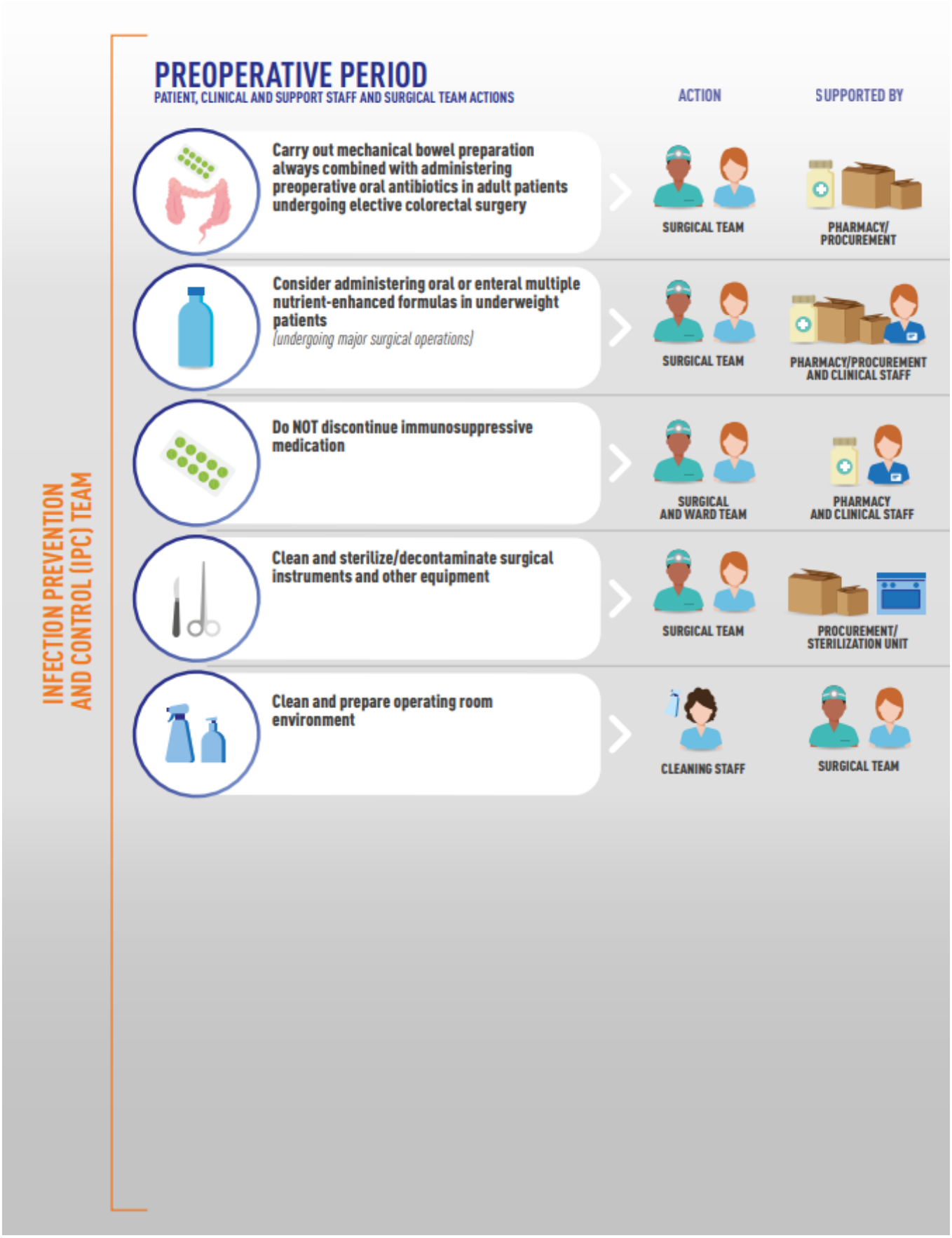

Figure 18. SSI prevention recommendations in the preoperative period (II). Extracted from the WHO web: "Do the right thing and the right time".

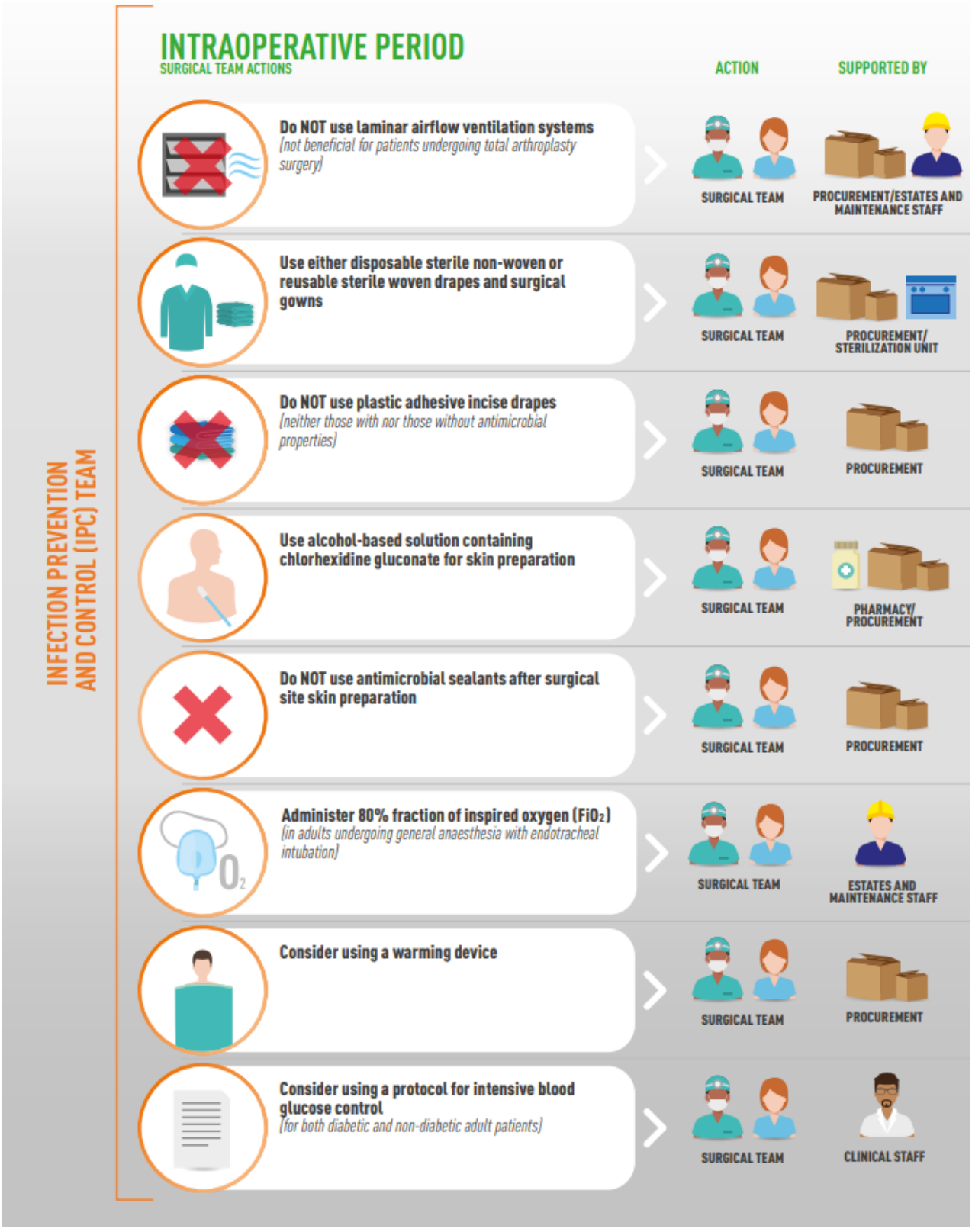

Figure 19. SSI prevention recommendations in the intraoperative period (I). Extracted from the WHO web: "Do the right thing and the right time to prevent surgical site infections".

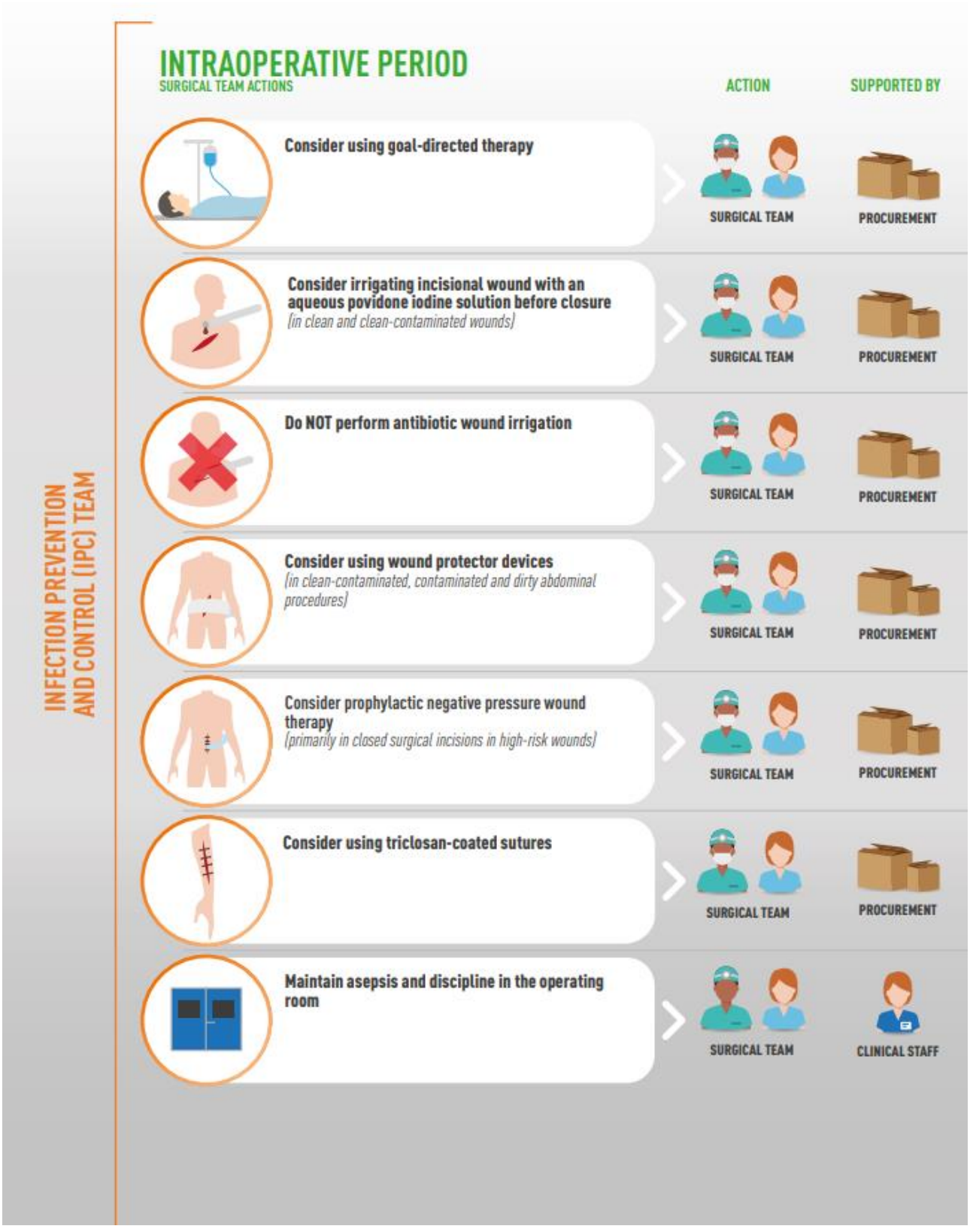

Figure 20. ***SSI prevention recommendations in the intraoperative period (II). Extracted from the WHO web: "Do the right thing and the right time to prevent surgical site infections".***

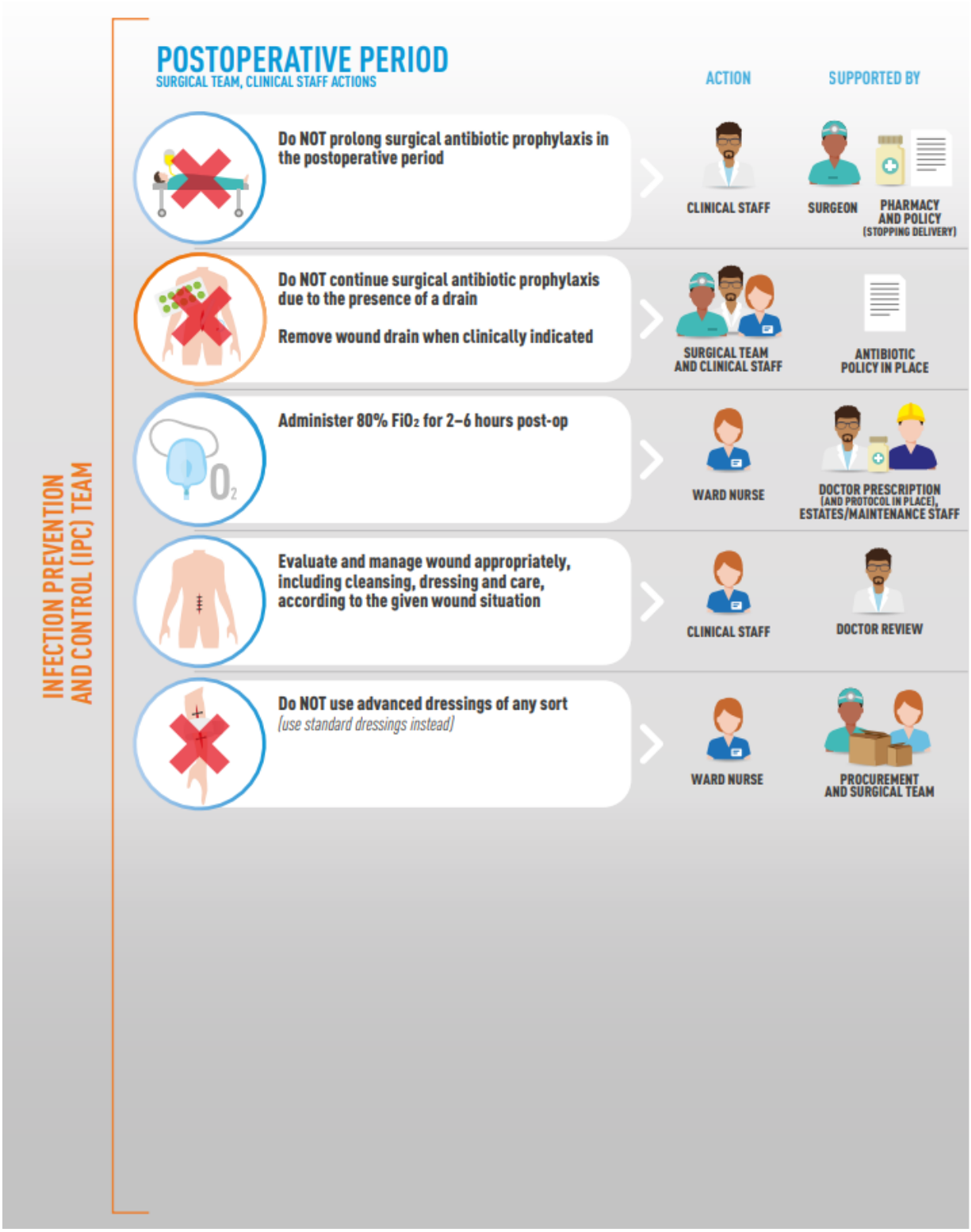

Figure 21. SSI prevention recommendations in the postoperative period. Extracted from the WHO web: "Do the right thing and the right time to prevent surgical site infections".

16.3. ANNEX 3. Protocol information sheet in Catalan

FULL D'INFORMACIÓ PER AL PACIENT

Estimat pacient,

Ens dirigim a vostè per informar-vos sobre l'estudi d'investigació "*Approaching elective colorectal surgical site infections: benefits of percutaneous radio-guided drain placement versus surgical reintervention to control the focus of infection"* en el qual volem convidar-lo a participar. Aquest estudi ha estat aprovat pel Comitè d'Ètica d'Investigació Clínica pels centres organitzadors i participants.

L'objectiu d'aquesta fulla d'informació és exposar-li tota la informació necessària, de manera comprensible i suficientment resumida per tal de que pugui valorar si vol participar de l'estudi.

La participació d'aquest estudi és totalment voluntària i pot retirar el seu consentiment en qualsevol moment, sense necessitat de cap explicació ni de cap perjudici. Tindrà un temps de reflexió, en el qual pot consultar qualsevol dubte no només amb l'investigador principal de l'estudi sinó també amb qualsevol persona que consideri oportuna.

- **Introducció i objectius de l'estudi:**

Les infeccions de localització quirúrgica segueixen essent una de les principals complicacions de qualsevol tipus de cirurgia, i s'associen a elevada morbiditat i disminució de qualitat de vida. No només segueixen tenint una incidència elevada tot i l'aplicació de mesures d'asèpsia intra-quirúrgiques i la millora en les tècniques quirúrgiques, sinó que segueixen associant una taxa gens despreciable de mortalitat.

Aquest impacte socioeconòmic és especialment rellevant en el context de les cirurgies colorectals, ja que d'entrada ja parteixen d'un ambient o context anatòmic amb major càrrega microbiana.

La resolució de les infeccions de localització quirúrgica consisteix en un maneig multidisciplinari en el que no només la teràpia antibiòtica tindrà un paper important sinó que també caldrà fer un desbridament de la zona infectada. Aquesta secció del tractament es pot realitzar tant mitjançant la col·locació d'un drenatge radioguiat de manera percutània o bé fent un control d'infecció mitjançant la re-intervenció quirúrgica, i de manera actual la decisió terapèutica d'escollir una o altre opció recau sobre l'equip quirúrgic.

Així doncs, el nostre estudi o projecte es basa en valorar l'impacte sobre les taxes de mortalitat, re-ingressos i els dies d'estada hospitalària de la col·locació del drenatge radioguiat, tècnica menys invasiva, en comparació a la re-intervenció quirúrgica, per poder recollir evidència que ajudaria a definir perfils quirúrgics i indicacions per a protocol·litzar cada intervenció segons les característiques de cada pacient.

- **Característiques necessàries per participar a l'estudi:**

El convidem a participar ja que vostè compleix els criteris d'inclusió i no compleix els criteris d'exclusió, que serien els següents:

Criteris d'inclusió:

- Pacient major de 18 anys
- Ha estat sotmès a una cirurgia colorectal electiva
- Ha estat diagnosticat d'una infecció de localització quirúrgica d'òrgan/espai en els 30 dies posteriors a la cirurgia colorectal electiva
- Disponibilitat per fer un seguiment de tres mesos de durada posteriors a la data de la cirurgia.

Criteris d'exclusió:

- Absència de signes d'infecció en el moment de la cirurgia
- No accés a la història clínica
- Realització de cirurgia urgent colorectal
- Incapacitat de realitzar el seguiment de tres mesos de durada posteriors a la data de la cirurgia.

- **Què haig de fer si decideixo participar?**

Si decideix participar de l'estudi, primerament ha de signar el consentiment informat, a través del qual vostè dona permís als investigadors d'accedir i recollir les seves dades personals. Durant la primera visita amb l'equip de recerca rebrà una explicació de tot el procediment de l'estudi, i en el qual es verificaran els criteris d'inclusió i exclusió per decidir finalment si pot ser participant.

Li recordem que les dades que recolliran els investigadors es recolliran de manera anònima, i que podrà retirar la seva participació de l'estudi en qualsevol moment, sense que això li generi cap perjudici.

- **Protecció de dades personals i confidencialitat:**

Com s'ha comentat anteriorment, totes les dades i informació que recollirem es farà de manera confidencial seguint el "Reglamento (UE) 2016/679 del Parlamento Europeo y del Consejo, del 27 de abril del 2016, relativo a la protección de las persones físicas en lo que respeta al tratamiento de datos persones y a la libre circulación de estos datos", i també segons la "Ley Orgánica 3/2018 del 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales".

Per poder garantir el tractament anònim de les dades, el que es farà és una assignació de codis numèrics, que identificaran a cada pacient.

En la publicació dels resultats de l'article i conjuntament: conferències i congressos; les dades continuaran essent tractades de forma anònima.

- **Beneficis. S'obtindrà algun benefici per participar de l'estudi?**

Aquest estudi és un assaig quasi experimental amb l'objectiu de recollir evidència per tal de generar (en un futur) protocols d'actuació. No s'obtindrà cap benefici, ni econòmic ni de cap altre tipus de compensació. D'altra banda, aquest estudi generarà evidència científica que es traduirà en un benefici econòmic i científic i també social.

- **Riscos. Quins inconvenients pot comportar participar de l'estudi?**

L'estudi no comporta cap risc o inconvenient afegit, ja que les dues tècniques de resolució de la infecció de localització quirúrgica estan aprovades i indicades pel tractament d'aquesta patologia i s'utilitzen actualment a la pràctica clínica. Els hospitals escollits com a participants de l'estudi tenen equips quirúrgics i de radio-intervencionisme formats i amb experiència en aquest àmbit.

Moltes gràcies per la seva col·laboració.

Es pot posar en contacte amb l'investigador principal en qualsevol moment per comunicar els seus dubtes.

Firma del pacient ***Firma del membre de l'equip de recerca***

Firmat a ____, dia ____ del mes _____ i any_____

Coordialment,

Equip d'investigació de l'estudi "*Approaching elective colorectal surgical site infections: benefits of percutaneous radio-guided drain placement versus surgical reintervention to control the focus of infection".*

16.4. ANNEX 4- Protocol information sheet in Spanish

HOJA DE INFORMACIÓN PARA EL PACIENTE

Estimado paciente,

Nos dirigimos a usted para informarle sobre el estudio de investigación llamado "*Approaching elective colorectal surgical site infections: benefits of percutaneous radio-guided drain placement versus surgical reintervention to control the focus of infection"* en el que queremos invitarlo a participar. Este estudio ha estado aprobado por el Comité de Ética e Investigación Clínica por los centros organizadores y participantes.

El objetivo de esta hoja informativa és exponerle toda la información necesaria, de manera comprensible y suficientemente resumida para que pueda valorar si quiere participar del estudio.

La participación del estudio es totalmente voluntaria y puede retirar su consentimiento en cualquier momento, sin necesidad de dar explicaciones ni de que reciba ningún perjuicio. Se le dará un tiempo de reflexión, en el que puede exponer todas sus dudas no solo al investigador principal del estudio, sino también a cualquier persona que usted considere oportuna.

- **Introducción y objetivos.**

Las infecciones de localización quirúrgica siguen siendo una de las principales complicaciones de cualquier tipo de cirugía, y se asocian a elevada morbilidad y disminución de la calidad de vida. Se mantienen con tasas de incidencia elevada aún con todas las medidas aplicadas de asepsia intra quirúrgica y la mejora de las técnicas quirúrgicas, sino que también siguen asociándose con tasas nada despreciables de mortalidad.

Este impacto socioeconómico es especialmente relevante en el contexto de las cirugías colorrectales, ya que parten de la base de un ambiente o contexto anatómico con mayor carga microbiana.

La resolución de las infecciones de localización quirúrgica consiste en un manejo multidisciplinario en el que no sólo la terapia antibiótica va a tener un papel importante, sino que también va a ser necesaria el desbridamiento de la zona infectada. Esta sección del manejo terapéutico se puede realizar de dos formas: con la colocación de un drenaje radioguiado de manera percutánea o haciendo un control de la infección mediante la reintervención quirúrgica. Actualmente, la decisión de escoger una o otra opción, recae sobre el equipo quirúrgico.

Así pues, nuestro estudio o proyecto se basa en valorar el impacte sobre las tasas de mortalidad, reingresos y los días de estada hospitalaria de la colocación del drenaje radioguiado (técnica menos invasiva) en comparación con la reintervención quirúrgica, para poder recoger evidencia que ayudaría a definir perfiles quirúrgicos e indicaciones para futuros protocoles de cada intervención según las características de cada paciente.

- **Características indispensables para participar del estudio:**

Lo invitamos a participar de nuestro estudio porque cumple los criterios de inclusión y no cumple los de exclusión, que sería los siguientes:

Criterios de inclusión:

- Paciente mayor de 18 años
- Ha estado sometido a una cirugía colorrectal electiva
- Ha estado diagnosticado de una infección de localización quirúrgica órgano/espacio en los 30 días posteriores a la cirugía colorrectal electiva.
- Capacidad de realizar un seguimiento de tres meses de duración a los pacientes sometidos a la cirugía

Criterios de exclusión:

- Presencia de signos de infección en el momento de la cirugía
- Incapacidad de acceder a la historia clínica
- Realización de una cirugía urgente
- Incapacidad de hacer un seguimiento de tres meses de duración a los pacientes sometidos a la cirugía.

- **¿Qué tengo que hacer si decido participar?**

Si usted decide participar del estudio, deberá signar el consentimiento informado, a través del cual usted da permiso a los investigadores para acceder y recoger sus datos personales. Se le asignará también una visita con el investigador de manera que reciba una explicación de todo el procedimiento del estudio, i en el que se verificarán los criterios de inclusión y exclusión para determinar si finalmente puede ser participante del estudio.

Le recordamos que los datos que van a recoger los investigadores se van a recoger de forma anónima y podrá retirar su participación en cualquier momento, sin que eso le genere ningún prejuicio.

- **Protección de datos personales y confidencialidad:**

Como se ha descrito anteriormente, todo dato o información que vamos a recoger, se hará de forma confidencial, en consonancia con Reglamento (UE) 2016/679 del Parlamento Europeo y del Consejo, del 27 de abril del 2016, relativo a la protección de las personas físicas en lo que respeta al tratamiento de datos persones y a la libre circulación de estos datos", i també según la "Ley Orgánica 3/2018 del 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales" y también según la "Ley Orgánica 3/2018 del 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales".

Para poder garantizar el tratamiento anónimo de los datos, se asignará un código numérico que identificaran a cada paciente.

En la publicación de los resultados del artículo y conjuntamente en conferencias y congresos, los datos continuaran siendo tratados de forma anónima.

- **Beneficios. ¿Se va a obtener algún beneficio para participar del estudio?**

Este estudio és un ensayo cuasi experimental con el objetivo de recoger evidencia para generar (en un futuro) protocoles de actuación. No se va a obtener ningún beneficio, ni económico ni de ningún otro tipo de compensación. Por otro lado, el estudio generará evidencia científica que se traducirá en un beneficio económico y científico y también social.

- **Riesgos. ¿Qué inconvenientes puede comportar la participación de este estudio?**

El estudio no comportará ningún riesgo o inconveniente añadido, ya que las dos técnicas para resolver la infección de localización quirúrgica están aprobadas e indicadas para el tratamiento de esta patología y se usan habitualmente en la práctica clínica. Los hospitales que hemos escogido como participantes del estudio tienen equipos quirúrgicos y de radio intervencionismo con formación y experiencia en este campo.

Muchas gracias por su colaboración.

Se puede poner en contacto con el investigador principal en cualquier momento para comunicar sus dudas.

Firma del paciente ***Firma del miembro del equipo de investigación***

Firmado a ____, día ____ del mes _____ y año_____

Cordialmente,

El equipo investsigador del estudio "*Approaching elective colorectal surgical site infections: benefits of percutaneous radio-guided drain placement versus surgical reintervention to control the focus of infection".*

16.5 ANNEX 5- Informed consent document in Catalan

FORMULARI DE CONSENTIMENT INFORMAT

Consentiment de l'estudi "*Approaching elective colorectal surgical site infections: benefits of percutaneous radio-guided drain placement versus surgical reintervention to control the focus of infection*" explicat i donat per l'investigador responsable _____ _____ amb DNI/Passaport núm. _____, treballador del centre _____ _____.

Sr/Sra. _____ Amb DNI/Passaport núm. _____ i domicili a _____

DECLARO QUE:

1. He llegit la Fulla d'Informació, comprenent tots els beneficis i riscos que pot comportar, i he pogut aclarir qualsevol dubte de forma satisfactòria.
2. La meva participació és voluntària i que sé que em puc retirar o sol·licitar que retirin les meves dades i sempre que vulgui, sense donar cap explicació.
3. He estat informat/da per l'investigador o membre de l'equip d'investigació en què consisteix la meva implicació en l'estudi.
4. Dono permís per la utilització de les meves dades i de la meva història clínica pels investigadors per fins relacionats amb l'estudi.
5. Dono permís que els investigadors guardin els resultats i les dades de seguiment en el registre corresponent amb el fi d'analitzar-les per l'estudi.
6. Comprenc que no rebré remuneració per la meva participació en aquest estudi.
7. Comprenc que la informació de l'estudi serà confidencial i que cap persona no autoritzada tindrà accés a les dades.
8. Declaro que se m'ha entregat una còpia del Full d'Informació i una còpia d'aquest document firmat.

Firmes:

Accepto ☐ No accepto ☐	
Participant	*Persona de l'estudi responsable de donar el consentiment*

Firmat a _____, dia ____ del mes ____ i any ____

16.6 ANNEX 6 – Informed consent document in Spanish

FORMULARIO DEL CONSENTIMIENTO INFORMADO

Consentimiento del estudio "*Approaching elective colorectal surgical site infections: benefits of percutaneous radio-guided drain placement versus surgical reintervention to control the focus of infection*" explicado i entregado por el investigador responsable ___ _____ amb DNI/Pasaporte núm. _____trabajador del centro _____.

Sr/Sra. _____ con DNI/Pasaporte núm. _____ i domicilio a _____

DECLARO QUE:

1. He leído la Hoja de Información, comprendiendo los beneficios y riesgos que puede comportar, y he podido aclarar cualquier duda de forma satisfactoria.
2. Mi participación es voluntaria i que me puedo retirar o solicitar la retirada de mis datos siempre que quiera, sin necesidad de dar ningún tipo de explicación.
3. He sido informada por el investigador en qué consiste mi implicación en el estudio.
4. Doy permiso para la utilización de mis datos y de mi historia clínica por los investigadores con fines relacionados con el estudio.
5. Doy permiso para que los investigadores guarden los resultados y los datos de seguimiento en el registro correspondiente con el fin de analizarlos para el estudio.
6. Comprendo que no voy a recibir ningún tipo de remuneración por mi participación en el estudio.
7. Comprendo que la información del estudio va a ser confidencial y que ninguna persona no autorizada tendrá acceso a los datos.
8. Declaro que se me ha entregado una copia de la Hoja de información y una copia de este documento firmado.

Firmas:

Acepto ☐ No acepto ☐	
Participante	*Persona del estudio responsable de dar el consentimiento*

Firmado en _____, día ____ del mes ____ y año ____