CLINICAL TRIAL PROTOCOL

GROIN SURGICAL SITE INFECTION AFTER INTRADERMAL SUTURE CLOSURE VERSUS METALLIC STAPLE CLOSURE: STUDY PROTOCOL OF A PRAGMATIC, MULTICENTER, OPEN-LABEL, PARALLEL GROUPS, RANDOMIZED CLINICAL TRIAL (VASC-INF)

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SUMMARY

VASC-INF TRIAL
TITLE: GROIN SURGICAL SITE INFECTION AFTER INTRADERMAL SUTURE CLOSURE VERSUS METALLIC STAPLE CLOSURE: STUDY PROTOCOL OF A PRAGMATIC, MULTICENTER, OPEN-LABEL, PARALLEL GROUPS, RANDOMIZED CLINICAL TRIAL (VASC-INF)
TRIAL REGISTRATION: Clinicaltrials.gov: NCT05434182
FUNDING This work is supported by B. Braun®. Funding will cover expenses related to clinical trial administrative procedures, Institutional Review Board (IRB) and Regulatory Authority feed, and services provided by the Contract Research Organization (CRO) for study monitoring, pharmacovigilance, e-CRF preparation, statistical analysis, and the final report. Costs associated with surgical procedures and the complementary tests will be covered by the Catalan Institute of Health and will not add additional expenses. Investigators will not receive any financial compensation for conducting the study. The corresponding author will have full access to all study data and is responsible for submitting the paper for publication.
ROLE OF SPONSOR The Sponsor will systematically review the study quality management to identify, evaluate and control risks to study critical processes and data that would affect patient safety and reliability of study data.

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INTRODUCTION

Surgical site infections (SSI) are among the most common and fearsome complications in vascular surgery, given its high morbidity and mortality rates[1]. SSI is associated with a two – to three-fold increased risk of death and a 60% increased risk of requiring postoperative intensive care support. It increases the length of hospital stay by 7-12 days, patients are five times more likely to require readmission, and direct healthcare costs raise at least US$5000[2–4]. SSI is an infection that occurs after surgery in the part of the body where the surgery took place[5,6]. It can be superficial, or deep, depending on its characteristics[7]. The groin is the most common infection site in vascular surgery, because it is a folding area with many lymph glands and is close to genitalia[8]. SSI incidence after vascular surgery has dropped from almost 30%[9] in the 1980s to 20%[10] in the 2000s and currently is approximately 10%[11]. This reduction may be due to improvements in asepsis measures and operative time. A 2021 meta-analysis on strategies to prevent inguinal SSI reported that using intradermal sutures could associate a lower rate of SSI[12]. One of the papers presents a retrospective SSI incidence analysis among 330 patients who underwent arterial vascular intervention through a groin incision. Intradermal suture closure was performed in 262 patients, of whom 24 (9.2%) presented SSI, while staples closure was conducted in the remaining 68, of whom 17 (25%) developed SSI[13]. Another paper, published in 2018, compared the infection rate before (2012-2015) and after (2015-2016) the implementation of a dedicated SSI prevention protocol, analyzing among other parameters, the inguinal closure technique (*i.e.*, intradermal suture Vs, metallic staples). The results were promising, as among the 18 patients with an SSI, 16 (89%) had metallic staples, and only 2 (11%) had intradermal sutures, being these results statistically significant[14].

OBJECTIVES

- Our primary objective is to estimate the SSI incidence (superficial and/or deep) associated with a femoral approach up to 28 (±2) days after surgery.
- Our secondary objectives are as follows:

  To estimate the incidence of other surgical wound complications (*e.g.*, seroma, hematoma, lymphorrhagia) up to 28 (±2) days after surgery.

  To estimate the incidence of sepsis in patients with SSI up to 28 (±2) days after surgery.

  To describe the timing of prophylactic antibiotic administration.

  To assess the association between nutritional status (measured by serum albumin levels) and femoral approach-related SSI up to 28 (±2) days after surgery.

  To assess the association between Body Mass Index (BMI) and femoral approach-related SSI up to 28 (±2) days after surgery.

  To assess the association between incision length and femoral approach-related SSI up to 28 (±2) days after surgery.

  To assess the association between surgery duration and femoral approach-related SSI up to 28 (±2) days after surgery.

  To assess the association between the kind of surgery performed and femoral approach-related SSI up to 28 (±2) days after surgery.

  To assess the association between length of hospital stay before surgery and femoral approach-related SSI up to 28 (±2) days after surgery.

  To assess the association between foot lesions (Rutherford ischemic stages 5 or 6) and femoral approach-related SSI up to 28 (±2) days after surgery.

  To estimate the SSI incidence (superficial and/or deep) associated with the femoral approach up to 84 (±7) days after surgery.

DESIGN

- **STUDY SETTING**

We present a pragmatic, multicenter, randomised clinical trial, approved by the Research Ethics Committee of the Bellvitge University Hospital (PR047/22) and registered on clinicaltrials.gov (NCT05434182). It will be performed in the Bellvitge University Hospital, Germans Trias i Pujol University Hospital, and Trieste University Hospital. These are all specialised healthcare centers with all the means necessary to carry out complex surgeries.

- **ELEGIBILITY CRITERIA**

All adult patients undergoing revascularisation surgery requiring a femoral approach who meet all the inclusion criteria and none of the exclusion criteria will be enrolled in this trial. Patients will be informed about the trial and will be invited to participate. All potential participants will be notified that the surgical procedure will be conducted per standard clinical practice. We will only randomise the type of skin closure (*i.e.*, intradermal sutures or metallic staples).

Patients can be enrolled in the trial if all of the following criteria apply:

1. Adult patients (≥18 years old)
2. Both genders
3. Diagnosed with chronic lower limb ischemia or aortic, iliac, or femoral aneurysm
4. With a scheduled surgery for one of the following indications:
    a. Femoropopliteal bypass
    b. Femorodistal bypass
    c. Aortobifemoral bypass
    d. Axillofemoral or axillobifemoral bypass
    e. Femorofemoral bypass
    f. Femoral endarterectomy
    g. Femoral approach for exclusion of an aortic aneurysm
5. Surgical procedure with an incision perpendicular to the groin fold
6. Patients who undergo both unilateral or bilateral surgical approaches. **Note:** we will consider one patient as one intervention (*i.e.*, bilateral approaches will be quantified as one single femoral approach). In the case of bilateral procedures, the closure technique

will be the same for both sides.

7. Patients who sign the written informed consent

Patients will be automatically excluded if any of the following criteria apply:

1. Background of a previous surgical intervention in the groin
2. Femoral approach carried out in a surgical emergency setting
3. Femoral approach performed due to a femoral pseudoaneurysm
4. A surgical procedure performed with a transverse/oblique incision to the inguinal fold
5. A patient who withdraws consent to participate in the trial

- **RANDOMIZATION, MASKING, DATA COLLECTION AND MONITORING**

Participants will be randomly assigned in a 1:1 ratio to intradermal suture (experimental group) or metallic staples (control group), using a computer-generated random sequence created with R version 4.1.0 (R Foundation for Statistical Computing, Vienna, Austria) for Windows® stratified by trial site. The randomization sequence was developed by a third-part statistician uninvolved with any other aspect of the trial. Patients will be randomized on the day of surgery prior to groin closure. The surgical team will remain unaware of the treatment assignment until subcutaneous tissue closure, when the nurse will disclose it and inform the team. Given the nature of the intervention, neither patients, surgeons, nor investigators will remain blinded to treatment allocation once it was undertaken. No masking technique will be performed. Data collection will be performed using an *ad hoc*-created electronic Case Report Form (eCFR) on the Research Electronic Data Capture (REDCap®) Platform, which generated an anonymized database. Each participant will be assigned a computer-generated code to ensure anonymity. Baseline data will include age, sex, body mass index, smoking history, past medical history (hypertension, diabetes, dyslipidemia, heart disease, stroke, chronic obstructive pulmonary disease, chronic kidney disease, human immunodeficiency virus [HIV]), blood-test results (plasma albumin, white blood cell count, hemoglobin, platelets, sodium, potassium, creatinine, glomerular filtration rate [GFR]), and surgical indication. For patients with a Rutherford ischemic stage 5 or 6, the infection status of any existing ulcer will be also documented based on the medical history. Additional data that will be collected include type of surgery, incision length, surgeon in charge of skin closure (staff vs. resident surgeon), prosthetic material type, operative time, number of days the patient was admitted to the hospital before the day of the surgery, and in-hospital stay. Operative time is defined as the time between the incision and the end of skin closure. The incision length will be gathered extending the edges of the incision after skin

closure.

Data will be securely stored with confidentiality protections in accordance with current local and European legislations on personal data protection. Independent monitoring will be performed throughout the study to ensure data accuracy, adherence to protocol, and to validate database entries against source documents.

- **OUTCOMES**

Our primary outcome measure is the number (percentage) of patients who present a femoral approach SSI up to 28 (±2) days after surgery.

Our secondary outcome measures are:

- Number (percentage) of patients with other surgical wound complications (*e.g.*, seroma, hematoma, lymphorrhagia) up to 28 (±2) days after surgery.
- Number (percentage) of patients who develop sepsis up to 28 (±2) days after surgery.
- Time of prophylactic antibiotic administration.
- Type of microorganisms' species isolated on the microbiological culture of skin, subcutaneous tissue, and/or SSI secretion sample up to 28 (±2) days after surgery.
- Type of antibiotic therapy used in patients with femoral approach-related SSI up to 28 (±2) days after surgery).
- Serum albumin levels
- BMI
- Surgery duration
- Number of days between hospital admission and surgical intervention
- Number (percentage) of patients who present a femoral approach SSI up to 84 (±7) days after surgery.
- Kind of surgery performed
- Presence of foot lesions (Rutherford ischemic stages 5 or 6)

- **PARTICIPANT TIMELINE**

The entire clinical trial is expected to last approximately 2.5 years. The first patient will be included in April 2022, and the last patient is expected to be included in October 2023. Afterwards, data collection processes and trial publication is scheduled for October 2024.

- **PROVISIONS FOR POST-TRIAL CARE**

This is a low-level interventional trial since both skin closure techniques are currently used in standard clinical care. The complementary diagnostic of follow-up procedures entails the same safety risks as those conducted in standard clinical practice. Therefore, *ad-hoc* insurance has not been hired for this trial, given that the participants are already covered by individual or collective professional civil liability insurance or equivalent financial guarantee of the healthcare center where the clinical trial will be conducted. Likewise, post-trial care will be performed by the patient's designated physician, as per standard clinical practice, following the same follow-up protocol that applies to the general population (*i.e.*, that does not participate in the trial).

INTERVENTION DESCRIPTION:

Once the subjects or their legally authorised representative sign the written informed consent, the study will begin. Randomisation will be performed by study team member on the day of the surgery, , and only the circulating nurse will know the result. Antibiotic prophylaxis will be administered and registered. Groin area hair clipping will be performed before entering the operating room (OpR). Then, asepsis of the surgical area will be served with 4% chlorhexidine and a steridrape will be placed. The surgical intervention will be performed with an incision perpendicular to the inguinal fold. For groin closure, the fascia and the subcutaneous tissue will be closed with a continuous absorbable filament suture (Vycril [Novosyn® 2/0]). At this moment, the circulating nurse will inform about the closure technique (as determined by random assignment). Both skin closure techniques are described as follows:

- **Metallic stapling**: the surgeon everts one of the edges of the skin. Likewise, the assistant everts the other edge. The surgeon then staples both skin edges together by applying pressure and activating the stapler mechanism. The staples should be placed 0.5cm apart and cover the entire incision length.
- **Intradermal suture** (Monosyn Braun® 4/0 absorbable monofilament): the surgeon chooses one of the wound's apexes to settle an anchoring dermal stitch. Subsequently, performing a mirror image at the opposing side, placing a dermal stitch at 0.5cm from the wound edge and always trying to keep the bite at the same length. The surgeon then alternates the stitching sides until reaching the other apex of the wound, performing five knots to secure the suture. Afterwards, passes the needle back deep through the edge, emerging it adjacent to the wound, thereby burring the knot.

Once the skin closure has been performed, a surgical dressing will be placed on the groin area, thereby finishing the surgery. The surgical dressing will not be uncovered for a 48-hour timeframe unless strictly necessary.

Criteria for Discontinuing or Modifying Allocated Interventions

Given the characteristics of this clinical trial, once the randomly assigned skin closure procedure has been performed, it cannot be modified. Participants may voluntarily

discontinue their participation in the clinical trial for any reason, at any time. The investigator may also decide at any time during the trial to temporarily interrupt or permanently discontinue the patients' participation in the clinical trial if it is deemed that continuation would be detrimental to or not in the participant's best interest. Similarly, the ethics committee or authorised regulatory authority can decide to halt or prematurely terminate the trial when new information becomes available whereby the rights, safety and well-being of trial participants can no longer be assured, when the integrity of the trial has been compromised, or when the scientific value of the trial has become obsolete and/or unjustifiable.

SCHEDULE OF ASSESSMENTS

1. Baseline visit (Screening and Enrollment): the baseline visit will be primarily performed in the Outpatient Clinic. However, if the subject is an inpatient, it will be conducted during hospitalisation. A clinical evaluation will assess if the subject meets all the inclusion criteria and none of the exclusion criteria. The subject will be informed about the trial procedures, as well as about its risks and benefits. The Patient Information Sheet (containing complete trial procedures' information) will be handled, and the subject or their legally authorised representative will be asked to sign the written informed consent. Once the written informed consent has been signed, the subject automatically becomes an enrolled study participant. Subsequently, we will gather demographic data, BMI, nutritional assessment (*i.e.*, serum albumin levels), past medical history and medical examination data. As in standard clinical practice, we will make preoperative assessments (chest radiography, electrocardiogram, and blood analysis).
2. Visit 1 (Day of the Surgical Intervention): participants will be randomly assigned to one of the study groups right before surgery through the electronic case report form (eCRF) itself (Research Electronic Data Capture software [REDCap®] platform). After surgery, the study team will record several data: the type of anesthesia, any incident during the surgical intervention, the procedures' duration, surgical wound length, the material used (vein, dacron, polytetrafluoroethylene, omniflow), closure technique performed and degree of the surgeon performing the incision and the closure (a trainee or a staff member).
3. Visit 2 (Hospital Stay): the surgical dressing will be uncovered 48 hours after surgery. Patients assigned to the control group (*i.e.*, metallic stapling skin closure) will have their staples removed seven days after surgery. Patients discharged before the seventh day will have their staples removed in the Outpatient Clinic. During the hospital stay, we will perform a daily surgical wound inspection. Postoperative blood tests and complications will be recorded. This data will be entered into the program on the day of hospital discharge.

4. Visit 3 (at 28 [±2] days after surgery): a face-to-face visit will be scheduled for 28 (±2) days after the surgery. The investigator will record (if any) the number and reason of extra medical consultation (including Emergency Department, hospital readmissions, and primary care either face-to-face or by phone). We will perform a surgical wound exam looking for any sign of SSI or other possible local complications (*e.g.*, seroma, hematoma, lymphorrhagia). We will record the microbiological culture results that could be pending by the time of hospital discharge.
5. Visit 5 (at 84 [±7] days after surgery): It will be a phone interview. The investigator will record (if any) the number and reason for extra medical visits (including Emergency Department, hospital readmissions, and primary care either face-to-face or by phone). We will ask about any symptoms related to surgical wound complications, and in case of detecting any alarming signs a face-to-face visit will be scheduled. The participant will be informed about the end of the study period and perform a standard follow-up protocol.

	Baseline visit	Visit 1	Visit 2	Visit 3: 28+-3 days after surgery	Visit 4: 84+-7 days after surgery
	Inclusion of the patient	Surgical intervention	In-hospital visit		
Inclusion/exclusion criteria	X				
Informed consent	X				
Demographic data	X				
Medical history	X		X		
Physical exploration	X		X	X	
Blood test	X		X		
Data from surgical intervention		X			
Surgical site infection registry			X	X	X
Admissions registry				X	X

ETHICS

This trial will be conducted according to the criteria set by the Declaration of Helsinky, ICH Good Clinical Practice standards, and applicable regulations. Patients will be informed that their participation in the trial is entirely voluntary and that they can withdraw their consent at any time, under no penalty risk whatsoever. The Investigator's participation in this study is free, voluntary, unpaid, and independent. By the current Spanish legislation (Royal Decree 1090/2015), this clinical trial has a low level of intervention since both skin closure techniques are currently used in standard clinical care. The results from this clinical trial are confidential and may not be transferred to third parties in any form or manner without written permission from the Sponsor. All individuals involved in the clinical trial are bound to this confidentiality clause in line with the Regulation (EU) 2016/678 of the European Parliament and of the Council of April 27th, 2016, on the protection of natural persons about the processing of personal data and on the free movement of such data, as well as other valid and applicable laws and regulations, such as the Spanish Organic Law 3/2018, of December 5th, on Personal Data Protection and Digital Rights Assurance. When obtaining a signature for the Written Informed Consent, the investigator will request written permission from the patient to access his/her data directly. With this permission granted, the patient's data may be examined, analysed, verified, and reproduced for the clinical trial evaluation.

Data will be anonymised and dissociated so that the corresponding patient cannot be identified. Patients will be assigned consecutive numbers as they are enrolled in the study, and these identification numbers (or codes) will be used in the eCRF; the full name of the patient will not be included in the eCRFs. The principal investigator of each center will keep an updated patient identification list containing the name, clinical history number, and the patient's identification number (or code) for the clinical trial. The study monitor may access the patient's identity and data related to the study monitoring procedures. Anyone with direct access to the data (Regulatory Authorities, Trial Monitors, and auditors) will take all possible precautions to maintain the confidentiality of patients' identities. It is the investigator's responsibility to obtain written informed consent from the study patients. The Trial Monitor's responsibility is to ensure that each patient has given their written consent to allow this direct access. The investigator shall ensure that the documents provided to the Sponsor do not contain the patient's name or any identifiable data.

STATISTICAL METHODS

Our primary endpoint is the number (percentage) of patients who present a femoral approach SSI up to 28 (±2) days after surgery. We intend to contrast:

- Null hypothesis (H_o): there is no difference in the SSI incidence related to the femoral approach between the metallic stapling skin closure and the intradermal suture skin closure.
- Alternative hypothesis (H_1): the SSI incidence related to the femoral approach when performing a metallic stapling closure differs from the incidence when performing an intradermal suture skin closure.

To our knowledge, no published prospective studies compare SSI incidence between staples and intradermal closure. Nonetheless, a 2018 retrospective Finnish study estimated an SSI incidence of 9.2% for intradermal suture skin closure and 25.0% for metallic stapling skin closure[13]. Under this assumption, 200 patients (100 per study group) would be necessary to reject the null hypothesis at a 5% significance level and a power of 80% using a two-sided $\mathcal{X}^2$ test with a 1:1 allocation to treatment groups. Accounting a possible dropout rate of 10%, 224 subjects should be enrolled (112 per study group).

All analyses related to the intervention efficacy will be based on the intention-to-treat (ITT) population, reported according to CONSORT guidelines, basis (as reported in the CONSORT guidelines), keeping all patients selected and randomized in the group in which they were initially included, regardless of adherence to the protocol. Safety analyses will be based on the safety population who have been operated on after randomisation. The demographic and clinical profiles of all included subjects will be described by the study group using statistics according to variable type.

The primary outcome measure will be compared using the $\mathcal{X}^2$ test. The magnitude of the intervention effect will be presented as a cumulative incidence ratio (CIR) at 28 (±2) days after surgery, along with a 95% confidence interval (95%CI). In the secondary outcomes, incidences will be compared using the $\mathcal{X}^2$ test and the magnitude of the effect will be presented as a CIR along with a 95%CI. A regression logistic model will be used to assess the effect of nutritional status, BMI, incision length, surgery duration, type of surgery, length of hospital before surgery, and femoral approach-related SSI up to 28 (±2) days after surgery.

Analysis will be performed using R® version 4.1.0 for Windows® [R Core Team (2020). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL: https://www.Rproject.org/].

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