

# Comparing the effectiveness of saline irrigation and Bactisure® solution in debridement surgery for acute periprosthetic joint infections

<b>Submission date</b> 24/10/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 19/12/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/11/2024	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Despite significant progress in orthopedic surgery, the prevalence of periprosthetic joint infections (PJI) remains persistent, and future increases are expected due to the rising number of joint arthroplasties. PJIs are intricately connected to biofilm-producing bacteria, which encase infected prostheses, impairing the effectiveness of antibiotics and the immune system. PJIs are categorized as acute (immature) or chronic (mature) based on the biofilm's maturity, each requiring distinct treatment approaches. Chronic PJIs typically necessitate the replacement of all prosthetic components to eliminate the infection. In contrast, acute PJIs with immature biofilms are traditionally managed with Debridement, Antibiotic, and Implant Retention (DAIR). However, to date, there hasn't been a conclusive direct clinical comparison (in vivo) demonstrating the superiority of one irrigation solution over others. Recently, there has been a growing interest in irrigation solutions with antibiofilm properties, exemplified by the pre-formulated Bactisure® irrigation solution, containing ethanol, acetic acid, sodium acetate, benzalkonium chloride, and sterile water. Importantly, this solution has exhibited promise in in vitro studies. The main objective of the research project is to evaluate the effectiveness (healing rate) of the pre-formulated Bactisure® irrigation solution in vivo, compared to a control group using saline solution, in cases of acute knee and/or hip periprosthetic infections treated with DAIR.

### Who can participate?

Patients over 18 years old with acute or hematogenous single hip or knee PJI who are eligible for debridement, antibiotic and implant retention (DAIR) surgery.

### What does the study involve?

The study involves patients with acute or hematogenous PJI who will undergo the standard DAIR surgery. The type of irrigation solution used during the surgery will depend on the assigned group, with Group 1 receiving a saline solution and Group 2 receiving the Bactisure® pre-formulated solution. The treatment allocation is determined through a scientific process known as randomization, in which there is a 50:50 chance of receiving either treatment. Importantly, the doctor will not have any involvement in this randomization process. It is worth

noting that apart from the irrigation solution, all other aspects of the surgical procedure are the same in both groups.

Furthermore, the study involves the collection of data from your medical records. Subsequently, clinical data needed for the clinical trial will be gathered during clinical follow-up appointments. These variables are typically evaluated in prosthetic infection surgery, and in addition to these, quality of life and functionality questionnaires will be administered.

What are the possible benefits and risks of participating?

While there is no financial compensation for participating in this study, involvement holds great significance. It has the potential to advance medical knowledge, leading to improvements in the treatment of patients with PJI. The implementation of the irrigation solution being studied could result in early infection eradication, thereby avoiding costly prosthetic replacements and reducing associated morbidity and mortality. Potential risks encompass complications associated with DAIR surgery, including incomplete resolution of infection, as well as standard surgical risks.

Where is the study run from?

Vall d'Hebron University Hospital (Spain)

When is the study starting and how long is it expected to run for?

Septembre 2022 to July 2025

Who is funding the study?

1. 2023 Dr Josep Trueta Scholarship offered by the Catalan Society of Orthopedic Surgery and Traumatology (SCCOT; Societat Catalana de Cirurgia Ortopèdica i Traumatologia) (Spain)
2. Septic and Reconstructive Surgery Unit within the Reconstructive Surgery of the Locomotor System Group at the Vall d'Hebron Institute of Research (VHIR) (Spain)
3. 2024 Carles Margarit Award from Vall d'Hebron Institute of Research (VHIR), recipient Rafael Oleo-Taltavull (Spain).

The funders had no role in the data collection, analysis, interpretation of the results, article writing, and decision to publish.

Who is the main contact?

Rafael Oleo, [rafael.oleo@vallhebron.cat](mailto:rafael.oleo@vallhebron.cat)

## Contact information

### Type(s)

Public, Scientific, Principal Investigator

### Contact name

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

IPPA-DAIR-SP

## Study information

### Scientific Title

Efficacy of the preformulated irrigation solution Bactisure® in acute periprosthetic joint infection debridement surgery: a randomized controlled trial

### Study objectives

This randomized clinical trial aims to determine whether the pre-formulated irrigation solution, Bactisure®, containing ethanol, acetic acid, sodium acetate, and benzalkonium chloride in sterile water, is more effective compared to saline irrigation as part of the debridement, antibiotic and implant retention (DAIR) procedure for acute periprosthetic joint infection (PJI). Effectiveness is defined as achieving lower reinfection rates.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

Approved 25/11/2022, Vall d'Hebron University Hospital Clinical Research Ethics Committee (CEIm) (Pg. Vall d'Hebron, 119-129, Barcelona, 08035, Spain; (+34) 934893891; ceic@vhir.org), ref: PR(AT)192/2022

### Study design

Single-centre interventional single-blinded randomized controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital, Medical and other records

## Study type(s)

Treatment, Efficacy

## Participant information sheet

See study outputs table

## Health condition(s) or problem(s) studied

Patients diagnosed with acute or hematogenous periprosthetic hip or knee infection (PJI) eligible for debridement, antibiotic and implant retention (DAIR) surgery

## Interventions

This single-center randomized controlled trial comprises two groups allocated in a 1:1 ratio. To achieve balanced patient distribution, a restrictive randomization method will be employed, which entails pairing cases for randomization. The first case is assigned to either Group 1 or Group 2, and the second case is placed in the opposite group. This process will be repeated for each new pair of cases.

During the DAIR surgery irrigation will be using a low-pressure pulsatile lavage system with the assigned irrigation solution at pre-intervention randomization:

Intervention Group: 3 L of saline solution, followed by 1 L of Bactisure®, and then another 3 L of saline solution (7 L in total).

Comparator Group: 3 L of saline solution, followed by 3 L of saline solution, and then another 3 L of saline solution (9 L in total).

## Intervention Type

Procedure/Surgery

## Primary outcome measure

Current primary outcome measure as of 22/07/2024:

Infection cure rate measured using the following criteria at the 12-month follow-up:

A case will be considered cured if it meets all of the following requirements:

1. Absence of local recurrence, indicated by the absence of dehiscence, exudation, or fistula
2. Radiographic evidence of no osteolysis
3. No ongoing suppressive antibiotic treatment
4. Absence of any re-interventions
5. No deaths related to periprosthetic infection

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Previous primary outcome measure as of 07/02/2024:

Infection cure rate measured using the following criteria at the 6-month follow-up:

A case will be considered cured if it meets all of the following requirements:

1. Absence of local recurrence, indicated by the absence of dehiscence, exudation, or fistula
  2. Radiographic evidence of no osteolysis
  3. No ongoing suppressive antibiotic treatment
  4. Absence of any re-interventions
  5. No deaths related to periprosthetic infection
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Previous primary outcome measure:

Infection cure rate measured using the following criteria at the 12-month follow-up:

A case will be considered cured if it meets all of the following requirements:

1. Absence of local recurrence, indicated by the absence of dehiscence, exudation, or fistula
2. Radiographic evidence of no osteolysis
3. No ongoing suppressive antibiotic treatment
4. Absence of any re-interventions
5. No deaths related to periprosthetic infection

### **Secondary outcome measures**

Current secondary outcome measures as of 22/07/2024:

1. Length of hospital stay, in days, measured using medical records at one timepoint
2. Potential postoperative complications (e.g. infections, re-operations, osteolysis) at hospitalization or in ambulatory controls measured using medical records at one timepoint
3. Microorganism identified on perioperative cultures, at hospitalization measured using standard laboratory methods at one timepoint
4. Pain level measured using the Visual Analogue Scale (VAS) Pain Score at 2, 6 and 12 months postoperatively
5. Patient functionality status measured using the Harris Hip Score (HHS) or Oxford Knee Score (OHS) at 6 months and 12 months post-surgery

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Previous secondary outcome measures as of 07/02/2024:

1. Length of hospital stay, in days, measured using medical records at one timepoint
2. Potential postoperative complications (e.g. infections, re-operations, osteolysis) at hospitalization or in ambulatory controls measured using medical records at one timepoint
3. Microorganism identified on perioperative cultures, at hospitalization measured using standard laboratory methods at one timepoint
4. Pain level measured using the Visual Analogue Scale (VAS) Pain Score at 2, 4 and 6 months postoperatively
5. Patient functionality status measured using the Harris Hip Score (HHS) or Oxford Knee Score (OHS) at 4 months and 6 months post-surgery

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Previous secondary outcome measures:

1. Length of hospital stay, in days, measured using medical records at one timepoint
2. Potential postoperative complications (e.g. infections, re-operations, osteolysis) at hospitalization or in ambulatory controls measured using medical records at one timepoint
3. Microorganism identified on perioperative cultures, at hospitalization measured using standard laboratory methods at one timepoint
4. Pain level measured using the Visual Analogue Scale (VAS) Pain Score at 2, 6 and 12 months postoperatively
5. Patient functionality status measured using the Harris Hip Score (HHS) or Oxford Knee Score (OHS) at 6 months and 12 months post-surgery

**Overall study start date**

01/09/2022

**Completion date**

01/07/2025

## Eligibility

**Key inclusion criteria**

1. Age >18 years old
2. Patients with hip or knee prostheses
3. Diagnosis of periprosthetic joint infection according to the criteria established in the Second International Consensus on Musculoskeletal Infections
4. Acute PJI: <6 weeks since the initial arthroplasty surgery
5. Acute hematogenous PJI: <3 weeks from symptom onset, documented bacteremia (positive blood culture) with the same microorganism in joint fluid
6. No previous debridement surgeries
7. Surgery performed: DAIR

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

50

**Total final enrolment**

50

**Key exclusion criteria**

1. Patients who do not voluntarily and without coercion agree to participate in this clinical trial
2. Patients under 18 years of age
3. Prosthetic reinfections or a history of multiple debridements
4. Known sensitivity or allergic reaction to ethanol, acetic acid, sodium acetate, or benzalkonium chloride
5. Diagnosis of Chronic PJI: the presence of fistula or >6 weeks
6. Multiple infected implants (>1)
7. Medically unfit for DAIR surgery
8. Pregnancy
9. Legal incapacity

**Date of first enrolment**

01/12/2022

**Date of final enrolment**

01/12/2024

## **Locations**

**Countries of recruitment**

Spain

**Study participating centre**

**Vall d'Hebron University Hospital**

Pg. Vall d'Hebron, 119-129

Barcelona

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## **Sponsor information**

**Organisation**

Vall d'Hebron Institut de Recerca

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**Sponsor type**

Research organisation

**Website**

<https://vhir.vallhebron.com/ca>

**ROR**

<https://ror.org/01d5vx451>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Catalan Society of Orthopedic Surgery and Traumatology

**Funder Name**

Fundació Institut de Recerca Hospital Universitari Vall d'Hebron

**Alternative Name(s)**

Vall d'Hebron University Hospital, Vall d'Hebron Hospital Research Foundation, Vall d'Hebron Institut de Recerca, VHIR, FIR-HUVH

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

Spain

## Results and Publications

**Publication and dissemination plan**

A variety of dissemination channels will be utilized to share information about the project and the study's results with clinicians, patients, and the general public, including:

1. The study protocol will be published in a peer-reviewed, open-access journal before the recruitment phase concludes.
2. Upon completion of the study, the trial's findings will be presented at both national and international meetings organized by orthopaedic surgeon-focused organizations. This will include events hosted by organizations such as the Spanish Society for Orthopaedics and Traumatology (SECOT) and the European Federation of National Associations of Orthopaedics and Traumatology (EFORT).
3. The study report will be published in high-impact, peer-reviewed medical and orthopaedic journals with a broad readership.

**Intention to publish date**

01/09/2025

**Individual participant data (IPD) sharing plan**

The datasets created and/or analyzed during the current study will be accessible upon a reasonable and justified request. To obtain access to the data, please contact Rafael Oleo (rafael.oleo@vallhebron.cat).

**IPD sharing plan summary**

Available on request



**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version 3		02/11/2023	No	Yes
<a href="#">Protocol article</a>		16/11/2024	19/11/2024	Yes	No