Patient Information Sheet for Participating in a Research Project

Study title	**Efficacy of the pre-formulated irrigation solution Bactisure® in acute periprosthetic joint infection debridement surgery: a randomized controlled trial**
Protocol/serial number	IPPA-DAIR-SP
Sponsor	Vall d'Hebron Institute of Research (VHIR)
Principal Investigator	Rafael Oleo
Centre	Vall d'Hebron University Hospital
Unit	Septic and Reconstructive Surgery Unit

Introduction

We are reaching out to provide you with information about a research study in the field of acute periprosthetic infection, and we invite you to participate. This study has received approval from a Research Ethics Committee. Our goal is to ensure that you receive accurate and sufficient information to make an informed decision about your participation. Please read this information sheet carefully, and we are here to address any questions you may have. You may also consult with any individuals you deem appropriate.

Voluntary participation and right to withdraw consent:

Please be aware that your participation in this study is entirely voluntary, and you have the right to choose not to participate or change your decision at any time. Your decision will not impact your relationship with your doctor, nor will it affect your treatment.

Background

Despite significant progress in orthopaedic 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 vitro studies.

Objectives:

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.

Study Procedures:

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.

Benefits:

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.

Discomforts and Potential Risks Related to Your Study Participation:

You will not experience any additional discomforts or risks due to your participation in the clinical trial. Any discomforts or risks will be those associated with standard clinical practice for periprosthetic infection debridement surgery, including postoperative pain, wound care, laboratory tests, control radiographs, and postoperative rehabilitation.

Protection of Personal Data:

Both the sponsor and the centre will ensure the confidentiality of your personal data collected during the study, in compliance with both national data protection laws and European data protection laws.

Contact in Case of Questions:

If you need more information about this study, you can contact the responsible investigator, Dr. Rafael Oleo from the Department of Orthopaedic and Traumatology Surgery, at Tel. 934893480 or rafael.oleo@vallhebron.cat