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Safety study on heat treatment of infected total hip implants

Submission date	Recruitment status	[_] Prospectively registered
03/04/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/08/2026	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
04/08/2026	Surgery	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Infection occurring after joint replacement surgery is a serious problem that can happen when certain types of bacteria form a layer called biofilm around the implant. This complication can be very harmful to patients. The usual way to treat early infections after a total hip replacement surgery is called Debridement, Antibiotics, and Implant Retention (DAIR). However, this treatment doesn't always work well, and when it fails, it can lead to more health problems and even death for the patient.

A new approach called Induction Heating of metal implants and direct heating of non-metal implants (IDH) has been developed. This method involves using heat to damage the bacterial biofilm, which can kill the bacteria and weaken the biofilm. This heating process can be added to the DAIR treatment to improve its success rate, which is called i-DAIR.

The idea behind this study is to see if it's safe to use heating alongside DAIR for patients who have a post-joint replacement infection after a total hip replacement surgery. This study is specifically looking at safety aspects such as whether the implant stays in place properly, whether there's any damage to the bone caused by the heat, which can be monitored using CT scans, and overall how many negative events happen during the treatment.

Who can participate?

Patients aged 18 years or older who are scheduled for DAIR for suspected PJI after hip replacement.

What does the study involve?

Enrolled patients will receive in addition to the standard of care, heat treatment of the extraosseous parts of the implant during surgery. Patients will be followed for a duration of 1 year with CT RSA migration analyses, clinical evaluation including infection parameters < 1 week, 3 months, 6 months and 1 year.

What are the possible benefits and risks of participating?

While the patients participating in this study may not directly derive any immediate benefits, the results of the study should improve the knowledge on the safety of induction heating during

DAIR which is a very promising new treatment for patients with prosthetic joint infections especially considering consistent in vitro findings of efficacy against mature bacterial biofilms, which are confirmed by other independent research groups.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: As IDH is an add-on to an existing treatment (DAIR), the duration is approximately 5 additional minutes duration of the DAIR surgery. The risk of thermal damage is very low as international safety thresholds for thermal dose (16CEM43) are adhered to and acceptable thermal limits to bone are not exceeded. The potential benefit, based on invitro studies, is the higher probability of success of the DAIR procedure.

Where is the study run from?
Leiden University Medical Center (Netherlands)

When is the study starting and how long is it expected to run for?
March 2024 to July 2027

Who is funding the study?
Implant Preservation Devices B.V. (Netherlands)

Who is the main contact?
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Contact information

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Public

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Additional identifiers

Protocol serial number
U1111-1306-4806

Study information

Scientific Title
Induction heating heated debridement antibiotics and implant retention (i-DAIR) safety study “i-DAIR study”

Acronym
i-DAIR

Study objectives
The hypothesis is that heating can be safely used during Debridement Antibiotics and Implant Retention (DAIR) for patients with prosthetic joint infection (PJI) after primary total hip arthroplasty (THA).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/03/2026, The Medical Ethics Committee Leiden The Hague Delft (Leiden University Medical Center Albinusdreef 2, Leiden, 2333 ZA, Netherlands; +31 71 526 3241; metc-ldd@lumc.nl), ref: NL-010239

Primary study design
Observational

Study design
Phased prospective cohort study

Study type(s)
Treatment, Safety

Health condition(s) or problem(s) studied
Prosthetic Joint Infection (PJI) after primary total hip arthroplasty who require a DAIR procedure

Interventions
Enrolled patients will receive in addition to the standard of care, heat treatment of the extraosseous parts of the implant during surgery. Patients will be followed for a duration of 1 year with CT RSA migration analyses, clinical evaluation including infection parameters < 1 week, 3 months, 6 months and 1 year.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Monitor the bone-implant interface for possible heat induced osteolysis/necrosis after IDH using CT at 3 months

Key secondary outcome(s)
1. Monitor the bone-implant interface for possible heat induced osteolysis/necrosis after IDH using CT at 6 months and 1 year follow-up
2. Determine the fixation of the femoral stem and acetabular cup after i-DAIR procedure measured using CT radiostereometric analysis (RSA)
3. Monitor these patients for any unexpected side effects during the first year post-operative

Completion date
01/07/2027

Eligibility

Key inclusion criteria
1. Age 18 years or older
2. Scheduled for DAIR for suspected PJI after primary THA
3. The patient has a primary THA of a brand/type that was tested during the ex vivo studies for having a safe heating profile for i-DAIR
4. Ability to give informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
110 Years

Sex
All

Total final enrolment
0

Key exclusion criteria

1. No informed consent
2. Pregnancy or plans for pregnancy during the study period (due to CT migration scans)
3. Medical condition precluding major surgery
4. Pacemaker
5. Hemi arthroplasties
6. DAIR for suspected PJI after revision surgery (regardless of reason)
7. One stage or two stage revision surgery for PJI instead of DAIR
8. Conversion of DAIR to one or two stage revision during the same surgical session
9. Primary THA implant is of a different type than tested during ex-vivo studies
10. Primary THA implant has not passed the safety profile during ex-vivo studies

Date of first enrolment
01/12/2024

Date of final enrolment
01/07/2026

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Center, dept Orthopaedics
Albinusdreef 2
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Sponsor information

Organisation
LUMC

ROR
https://ror.org/05xvt9f17

Funder(s)

Funder type
Industry

Funder Name
Implant Preservation Devices B.V.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available