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# INFORM - surgery for hip infection project

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|---|---|---|
| **Submission date**<br>28/01/2015 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>29/01/2015 | **Overall study status**<br>Completed | |
| **Last Edited**<br>13/02/2024 | **Condition category**<br>Surgery | |

## Plain English summary of protocol

Background and study aims
Hip replacement surgery is common, with over 86,000 cases in England and Wales in 2012. After surgery about 1% patients develop a deep infection in their artificial hip, called a prosthetic joint infection (PJI). If left untreated PJI can result in severe pain, disability and death. When an infection is found, there are two types of surgical treatment: a 1-stage revision involves removing the joint, thoroughly cleaning the infected area and implanting a new joint immediately; a 2-stage revision involves removing the joint, and delaying re-implantation for 3 to 6 months whilst treating with antibiotics. Both treatments are widely used but we don't know which has the best long-term outcomes for patients. The aim of this study is to find out whether there is any difference in patient-reported outcomes (pain, stiffness or physical function) after 1-stage or 2-stage revision hip surgery for PJI.

Who can participate?
Patients that have a prosthetic joint infection that needs surgery.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 have 1-stage revision surgery. Those in group 2 have 2-stage revision surgery. All participants are then followed up for the next 18 months. They are asked to complete questionnaires every 3 months, to assess their hip pain and function, quality of life and any costs incurred during their treatment. They attend two appointments with a research nurse to complete questionnaires and a walk test. A small number of participants and surgeons are also interviewed about their experiences of treatment and participation in the trial. Participants who decide against the randomised trial are asked to join a monitoring group. This group have treatment-as-usual, and then complete questionnaires at home. The monitoring group provide important information on the wider population of patients with hip PJI, including patient reported outcomes, control of infection and adverse events.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
14 hospitals in the UK and 3 in Sweden (UK)

When is the study starting and how long is it expected to run for?
January 2015 to February 2020

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Mr Simon Strange

# Contact information

### Type(s)
Scientific

### Contact name
Mr Simon Strange

### Contact details
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# Additional identifiers

### Protocol serial number
18159

# Study information

### Scientific Title
A multicentre randomised trial to compare 1-stage with 2-stage revision surgery for prosthetic hip joint infection

### Study objectives
The aim of this study is to determine if there is any difference in patient-reported outcomes (pain, stiffness or physical function) after 1-stage or 2-stage revision hip surgery for prosthetic joint infection (PJI).

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
NRES Committee South-West - Frenchay, 31/12/2014, ref: 14/SW/1166

### Primary study design
Interventional

### Study design
Randomised; Interventional and Observational; Design type: Not specified, Treatment, Qualitative

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Topic: Surgery; Subtopic: Surgery; Disease: All Surgery

### Interventions
Revision hip surgery
1-stage or 2-stage revision for infected prosthetic hip joint; Follow Up Length: 18 month(s)

### Intervention Type
Other

### Primary outcome(s)
Patient-reported hip pain, stiffness, function; Timepoint(s): WOMAC at 18 months post-randomisation

### Key secondary outcome(s)
1. Quality of life, measured using Euroquol EQ-5D-5L and HOOS
2. All hip-related complications (including continuing and reinfection) recorded throughout study period
3. Post-op pain, measured using the Brief Pain Inventory
4. Patient-reported hip function, measured using the Oxford Hip Score
5. Objective measure of hip function, measured using the 20 metre timed walk test
6. Depression and anxiety, measured using the Hospital Anxiety and Depression Score
7. Cost-effectiveness of interventions, measured using health resource use

### Completion date
28/02/2020

## Eligibility

### Key inclusion criteria
1. Age 18 or above
2. A clinical diagnosis of prosthetic hip joint infection
3. Require revision surgery (either 1-stage or 2-stage) to treat prosthetic hip joint infection, in the opinion of the treating consultant orthopaedic surgeon
Target Gender: Male & Female ; Lower Age Limit 18 years

### Participant type(s)
Patient

### Healthy volunteers allowed

No

### Age group
Adult

### Lower age limit
18 Years

### Sex
All

### Total final enrolment
177

### Key exclusion criteria
1. Unable or unwilling to undergo either 1-stage or 2-stage revision surgery
2. Lack capacity to give written informed consent

### Date of first enrolment
04/03/2015

### Date of final enrolment
31/08/2018

## Locations

### Countries of recruitment
United Kingdom

England

Sweden

### Study participating centre
**North Bristol NHS Trust**
Trust Headquarters
Beckspool Road
Frenchay
Bristol
United Kingdom
B16 1JE

## Sponsor information

### Organisation

North Bristol NHS Trust

**ROR**
https://ror.org/036x6gt55

# Funder(s)

**Funder type**
Government

**Funder Name**
National Institute for Health Research

**Alternative Name(s)**
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# Results and Publications

**Individual participant data (IPD) sharing plan**
Participant level data will be made available at the data.bris (University of Bristol Research Data repository) beginning 1 year following publication of the trial results. Access to data will 'controlled' and request forms can be found at http://www.bristol.ac.uk/staff/researchers/data/accessing-research-data/

**IPD sharing plan summary**
Stored in repository

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 31/10/2022 | 01/11/2022 | Yes | No |
| Results article | | 01/11/2022 | 13/02/2024 | Yes | No |
| Protocol article | protocol | 17/02/2016 | | Yes | No |

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|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |
| Other publications | What are patients' preferences for revision surgery after periprosthetic joint infection? A discrete choice experiment | 21/01/2020 | 13/02/2024 | Yes | No |
| Other publications | qualitative study | 03/08/2020 | 13/02/2024 | Yes | No |