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INFORM - surgery for hip infection project

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date

10/02/2014

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 228; UK Sample Size: 228; Description: RCT - 142 patients; Monitoring group - approx 80 participants

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
England

Sweden

United Kingdom

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

Sponsor information

Organisation
North Bristol NHS Trust

Sponsor details
Research & Innovation
Floor 3 Learning & Research Building
Southmead Hospital
Bristol
England
United Kingdom
BS10 5NB

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
1. Protocol paper
2. Trial results paper
3. Cost-effectiveness analysis paper
4. Dissemination of Best Practice Guidance

Intention to publish date
01/09/2022

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?
Protocol article	protocol	17/02/2016		Yes	No
Results article		31/10/2022	01/11/2022	Yes	No
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
Results article		01/11/2022	13/02/2024	Yes	No