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Effectiveness and cost-effectiveness of hip implant types in patients younger than 70 years undergoing primary elective total hip replacement

Submission date
09/08/2024

Recruitment status
Recruiting

Registration date
16/08/2024

Overall study status
Ongoing

Last Edited
21/10/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Over 100,000 hip replacements are performed each year in the UK. Around 90% of patients report good pain relief and mobility after surgery, and most implants last 25 years or more. Primary hip replacement involves replacing a damaged hip joint with an artificial implant that has two main parts. One part goes into the thigh bone and ends in a ball which fits into a socket or cup attached to the pelvis, making a ball-and-socket joint. Implants can be fixed to the bone with cement (cemented), without cement (uncemented), or cemented in the thigh bone and uncemented in the pelvis (hybrid). Cost ranges from £500 for some cemented to £2,000 for some uncemented implants. When an implant fails, for example, due to loosening or wear, it has to be re-done (revision surgery). Revision is a major operation, typically costing the NHS over £10,000 and it doesn't give patients the same benefits as first-time surgery. Cemented hip implants are safe, inexpensive, have a long track record, and offer the best value for money for men aged over 75 and women aged over 65 years. There is no high-quality evidence to suggest more expensive uncemented or hybrid implants are any better than cemented implants for younger patients. Yet three-quarters of NHS patients aged under 70 years receive uncemented or hybrid implants. The study is trying to find out which type of hip implant is best for patients under 70.

Who can participate?
Adult patients aged under 70 years old having primary elective total hip replacement surgery for osteoarthritis will be eligible to take part in HIPPY.

What does the study involve?
Patients who agree to take part will be randomly assigned to receive an uncemented, cemented, or hybrid implant. Patients will be asked to complete questionnaires before and after their surgery. The questionnaires will continue every year for 10 years. Study patients will also be asked permission for the study team to access their medical data from other routinely collected patient databases for 10 years after surgery.

What are the possible benefits and risks of participating?
Benefits: The research will help us to understand which hip implant is best in patients under 70. Study participants may have more contact with your local research team and can let them know if they have any problems.
Risks: Participants may not know which type of hip implant they are having before their surgery and will be asked to spend time completing questionnaires.

Where is the study run from?
Bristol Trials Centre, University of Bristol (UK)

When is the study starting and how long is it expected to run for?
July 2023 to July 2033

Who is funding the study?
The National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
The central trial team, hippy-trial@bristol.ac.uk

Contact information

Type(s)
Scientific, Principal investigator

Contact name
Dr Elsa Marques

Contact details
Musculoskeletal Research Unit
University of Bristol
Learning and Research Building
Southmead Hospital
Bristol
United Kingdom
BS10 5NB
+44 (0)1174147851
e.marques@bristol.ac.uk

Type(s)
Public

Contact name
Mrs Samantha Abbs

Contact details
Bristol Trials Centre
1-5 Whiteladies Road
Bristol
United Kingdom
BS8 1NU

+44 (0)1174554799
hippy-trial@bristol.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
340331

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 340331, CPMS 61955

Study information

Scientific Title
Effectiveness and cost-effectiveness of cemented, uncemented and hybrid hip implant prostheses in the younger total hip replacement patient: a randomised controlled trial

Acronym
HIPPY

Study objectives
An uncemented implant is superior to a cemented implant
A hybrid implant is superior to a cemented implant

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/06/2024, West Midlands - Coventry & Warwickshire REC (2 Redman Place, London, E20 1JQ, United Kingdom; +44 (0)207 104 8211, (0)207 104 8177, (0)207 104 8263; coventryandwarwick.rec@hra.nhs.uk), ref: 24/WM/0082

Study design
Multicentre three-group superiority randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
This study is a multi-centre, three-group, superiority randomised controlled trial with patient-level randomisation, internal pilot, embedded qualitative research and health economic analysis in patients under 70 years undergoing primary elective total hip replacement surgery. The study participants will be randomised using a web-based randomisation system (sealedenvelope).

Patients undergoing primary elective total hip replacement surgery will be randomised to receive either a cemented (reference), uncemented or hybrid hip implant prosthesis.

Cemented - both the femoral and the acetabular components are attached to the bone with cement. Polymethylmethacrylate or bone cement is used to fix the stem and the cup in position. Surgeons can use any brand and type of cement.

Uncemented - The femoral and acetabular components attach to the bone by osseo-integration (bonding at a molecular level directly between bone and implant). They are usually press-fit and rely initially on a tight fit of the implants within the bone.

Hybrid - the femoral component is cemented, and the acetabular component is uncemented. It allows for a variety of uncemented acetabular bearing surfaces including ceramics but paired with a cemented stem.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Revision surgery measured using routine data from linked patient databases and/or data reported by participants in questionnaires at 10 years post-randomisation

Key secondary outcome(s))
1. [variables used to measure] Cost-effectiveness of the three implant types at 10 years and for the remainder of the patients' lives. In secondary analyses, cost-effectiveness will also be estimated for implants characterized by fixation and bearing surface.
2. Yearly revision rates (descriptive) measured using data collected from patients on annual questionnaires to triangulate with or supplement our primary outcome data collection methods until the last follow-up of the trial. After the primary outcome at 10 years, further funding will be sought to collect revision rates using linkage to routine data at 5-year intervals.
3. Health-related quality of life and quality-adjusted life years (QALYs) measured using patient-completed EQ-5D-5L at baseline, 6- and 12-months post-randomisation and annually thereafter. The trial questionnaires will be complemented by linkage with the national PROMS database for EQ-5D-3L at baseline and 6 months after primary and revision surgeries for trial patients
4. Pain measured using the Hip disability and osteoarthritis outcome score (HOOS-12) pain scale at baseline, 6- and 12-months post-randomisation
5. Activity measured using the HOOS-12 activity limitations daily living score at baseline, 6- and 12-months post-randomisation
6. Function measured using the Oxford hip score (OHS) collected from linkage with the national PROMS database at baseline and 6 months after primary and revision surgeries for trial patients.
7. Capability measured using the ICECAP-A at baseline, 6- and 12-months post-randomisation
8. Return-to-work and usual activities measured using a bespoke questionnaire about absenteeism and presenteeism at 6-months post-randomisation, and the Work Productivity and

Activity Impairment (WPAI) questionnaire at 12 months post-randomisation
9. Resource use (initial patient stay) measured using data collected from patient medical records, linked data and participant questionnaires at 6- and 12-months post-randomisation

Completion date
01/07/2033

Eligibility

Key inclusion criteria
1. Between 18 and 69 years of age (inclusive) at the time of screening
2. Undergoing primary elective THR due to osteoarthritis (patients may also have other indications for THR in addition to osteoarthritis)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
69 years

Sex
All

Key exclusion criteria
Current key exclusion criteria as of 21/10/2025:

1. Not willing to consent
2. Receiving primary THR exclusively for reasons other than osteoarthritis (e.g., rheumatoid arthritis, etc.),
3. Patients requiring custom-made implants,
4. Non-elective patients
5. Patients who lack capacity
6. Patients paying privately for their surgery (including patients using health insurance)
7. Prisoner
8. Patients who have previously been randomised to the HIPPY trial

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Previous key exclusion criteria:

1. Not willing to consent
2. Receiving primary THR exclusively for reasons other than osteoarthritis (e.g., rheumatoid arthritis, etc.),
3. Patients with dysplastic osteoarthritis requiring custom-made uncemented implants,
4. Non-elective patients
5. Patients who lack capacity
6. Patients paying privately for their surgery (including patients using health insurance)
7. Prisoner

Date of first enrolment
21/08/2024

Date of final enrolment
30/06/2027

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
North Bristol NHS Trust

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 4.0	11/06/2025	21/10/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes