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Ceramic hip resurfacing vs total hip replacement

Submission date
11/12/2023

Recruitment status
No longer recruiting

Registration date
04/01/2024

Overall study status
Ongoing

Last Edited
17/06/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
There are two main types of hip replacement: hip resurfacing and total hip replacement. Hip resurfacing can be a treatment for hip osteoarthritis in younger, more active people. It is proven that being able to achieve a certain amount of exercise can lower the risk of some diseases that lead to death. Therefore if there is a type of hip replacement that can help people with hip osteoarthritis achieve a higher level of exercise, this will deepen the understanding of the best treatment to give. The main research questions that the study has been designed to answer are: 1) Is the H1 Implant non-inferior in terms of clinical success to a cementless total hip replacement? 2) Does the H1 Implant allow a higher level (minutes and/or intensity) of exercise compared to a cementless total hip replacement? The answers to these research questions will give more information to surgeons and patients so that they are better informed in the decision-making process relating to their hip replacement choices.

Who can participate?
Patients who have hip osteoarthritis who require a hip replacement.

What does the study involve?
Patients will be identified as potential participants when they attend clinic. If they choose to take part they will be randomly chosen to receive either a hip resurfacing or a total hip replacement. They will have the operation and then at various stages over the next 2 years they will be asked to wear an activity tracker, complete questionnaires about their hip and complete some simple physical exercises. After 2 years they will be told which type of hip replacement they had. The patients will also have x-rays taken of their hip at regular time points up to 10 years after their surgery.

What are the possible benefits and risks of participating?
There will be no immediate benefit to those taking part. However, there could be benefits to future hip replacement patients. There are general risks relating to all surgery and all hip replacement surgery which are not increased by being part of this research. The main specific risk linked to participating in this study is the extra radiation the patients will receive due to the x-rays.

Where is the study run from?
Imperial College London (UK)

When is the study starting and how long is it expected to run for?
September 2024 to April 2035

Who is funding the study?
1. National Institute for Health and Care Research (NIHR) (UK)
2. Embody Orthopaedic Limited (UK)

Who is the main contact?
1. Dr Mariam Al-Laith, m.al-laith@imperial.ac.uk
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Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
327954

ClinicalTrials.gov number
NCT06162195

Secondary identifying numbers
IRAS 327954

Study information

Scientific Title
The ACTIVE trial: a prospective randomised control trial of the H1 implant versus total hip replacement

Acronym
ACTIVE

Study objectives
The main research hypothesis is that the H1 Implant will be non-inferior to cementless total hip replacement in terms of composite clinical success.

The secondary research hypothesis is that the H1 Implant will be significantly better than cementless total hip replacement in terms of activity level, measured using various metrics.

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 13/03/2024, Sheffield Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 1048098; sheffield.rec@hra.nhs.uk), ref: 24/YH/0083

Study design
Prospective randomized (1:1) double-blinded multi-centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment, Efficacy

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
Osteoarthritis, hip inflammatory arthritis

Interventions
Intervention 1: The H1 Implant
Intervention 2: Cementless total hip replacement (THR)

The H1 Implant is a cementless, ceramic hip resurfacing arthroplasty (HRA) device. This study will randomise patients to receive either the H1 Implant or a primary cementless ceramic-on-poly or ceramic-on-ceramic total hip replacement (THR).

Randomisation will be performed using variable block randomisation with block sizes of 4, 6 and 8, with a 1:1 allocation to the 2 groups, with stratification across sites. This will ensure approximately equal numbers across groups and approximately the same number per group at each site (to control for differences in the trial population because of environmental, social and demographic factors) while allowing different total numbers at each site. It will also ensure that at any given time, the numbers in each group will be approximately equal, allowing the interim analyses to take place. The randomisation will be managed by the CRO via an electronic data capture (EDC) system, which uses a validated randomisation algorithm. Once a patient has consented, they will be assigned to a treatment group according to the pre-determined order inside the block. Stratification by site is recommended for multi-centre studies.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase IV

Drug/device/biological/vaccine name(s)
The H1 Implant, Cementless total hip replacement

Primary outcome measure
Clinical success measured using a composite clinical success score at 0, 6 weeks, 6, 12 and 24 months and 3, 5 and 10 years.

Secondary outcome measures
1. Physical activity measured using a wearable activity tracker at 6, 12 and 24 months
2. Physical performance measured using physical performance assessments at baseline, 6, 12 and 24 months
3. Activity measured using the patient-reported outcome measure (PROM) Hip Outcome Score (HOS) at baseline, 6 weeks, 6, 12 and 24 months
4. Activity measured using the PROM UCLA Activity Score at baseline, 6 weeks, 6, 12 and 24 months
5. Noise measured using a Noise Survey at 6 weeks, 6, 12 and 24 months

Overall study start date
01/09/2023

Completion date
01/04/2035

Eligibility

Key inclusion criteria
1. Patient requires unilateral primary hip arthroplasty due to primary osteoarthritis, osteoarthritis secondary to e.g. trauma, avascular necrosis or developmental hip dysplasia, or inflammatory arthritis
2. Patient is willing to comply with study requirements
3. Patient plans to be available through 24 months postoperative follow-up

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Patient has a BMI greater than 40 kg/m²
2. Patient has active infection or sepsis (treated or untreated)
3. Patient has insufficient bone stock at the hip (>1/3 necrosis of the femoral head or large and multiple cysts) or in general as in severe osteopenia or osteoporosis (Tscore < -2.5 as measured with BMD)
4. Patient is not skeletally mature
5. Patient meets the contraindication criteria of the control device
6. Patient already has another lower limb arthroplasty or arthrodesis or will require a further lower limb arthroplasty or arthrodesis within the subsequent 2 years
7. Patient lacks capacity to consent
8. Patient is unable to understand the native language of the country where their procedure is taking place

Date of first enrolment
01/09/2024

Date of final enrolment
01/06/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Charing Cross Hospital
Fulham Palace Road
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Sponsor information

Organisation
Embody Orthopaedic

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Sponsor type
Industry

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ROR
https://ror.org/018caxa54

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

Funder Name
Embody Orthopaedic Limited

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/04/2036

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan	version 1.01	29/01/2024	17/06/2024	No	No