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To evaluate the clinical outcome of a ceramic-on-ceramic hip resurfacing arthroplasty using the ceramic, non-porous, non-cemented H1 Hip Resurfacing Arthroplasty

Submission date 30/11/2020	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 09/12/2020	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 29/12/2021	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Hip surgery to restore function (hip arthroplasty) is usually necessary when the hip joint is worn or damaged so that mobility is reduced and the person is in pain even while resting. The most common reason for hip replacement surgery is osteoarthritis. Other conditions that can cause hip joint damage include rheumatoid arthritis, hip fracture, septic arthritis, disorders that cause unusual bone growth (bone dysplasia).

Hip resurfacing provides a new surface for the ball and socket that make up the hip joint. Unlike a total hip replacement, it retains more of the bone. During the procedure, the damaged surfaces of the femur head (ball of the thighbone) and the acetabulum (socket in the pelvis) are reshaped and replaced with a cover.

The aim of the H1 study is to assess the short, mid and long-term safety and function of the new H1 Hip Resurfacing implant. Resurfacing, rather than replacing, the hip has long been a desirable option, but owing to limitations in materials and design, most resurfacing products have now been withdrawn from the market. The H1 System represents the next generation of hip resurfacings, with superior design and material characteristics.

Who can participate?
Patients aged between 18 and 70 years who require primary hip arthroplasty due to degenerative joint disease and meet the study inclusion criteria.

What does the study involve?
Participants will receive treatment as usual, however they will need to attend more follow up visits in order to provide data for the study over the following 10 years.

What are the possible benefits and risks of participating?
Benefits: The H1 Hip resurfacing implant is designed to address the symptoms associated with a

degenerated hip. In addition, to eliminating pain and restoring mobility, receiving this implant may reduce the amount of bone that must be removed. Participants will also be closely monitored for 10 Years. The device has not been studied clinically and so benefit is not assured. There are no other clear benefits to the participant from taking part. However, the information we get from this research might help in the future with management of joint disease.
Risks: Any operation to replace or resurface the hip carries risks, so the decision to proceed with a hip arthroplasty of any sort needs to be taken with caution. The potential benefit of a pain free hip has to be balanced with the risks of the operation causing an unexpected problem of some sort.

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 2017 to September 2032

Who is funding the study?
Embody Orthopaedic Limited (UK)

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

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT03326804

Integrated Research Application System (IRAS)
213102

Study information

Scientific Title
H1 Hip Resurfacing Arthroplasty

Study objectives
The primary hypothesis of the study is that the H1 implant will demonstrate non-inferiority in terms of survivorship compared to the Birmingham Hip Replacement. The secondary hypothesis is that the H1 implant will be demonstrated to be superior in terms of toxicology compared to the Birmingham Hip Replacement

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/09/2017, East of England – Cambridge Central Research Ethics Committee (Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8388; cambridgecentral.rec@hra.nhs.uk), ref: 17/EE/0330

Primary study design
Observational

Study design
Multi-centre prospective non-randomised observational study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hip arthroplasty

Interventions
Patients partaking in this investigation shall undergo hip surgery to have an H1 hip resurfacing implanted. A smaller cohort of patients shall additionally have small beads inserted into the bone surrounding the implant during the hip surgery, which will allow closer post-operative monitoring of the implant.

As part of this study, for the main cohort of patients, the following events will take place in addition to the standard of care which would be received.
1. Demographic information and medical history will be recorded before surgery
2. X-rays of the hip will be taken post-operatively at 1 year, 2 years, 3 years, 5 years and 10 years.
3. Pre-operatively, and post-operatively at 6 weeks, 6 months, 1 year, 2 years, 3 years, 5 years, 7 years and 10 years, participants will be asked to complete questionnaires (EQ5D, Oxford Hip Score and Imperial Score) to evaluate hip function (these can be complete onsite or at participants own convenience). In addition, participants will be asked to complete a paper-based

questionnaire (Harris Hip Score).
4. All participants will be followed up for 10 years and a final evaluation will occur at the end of the 10-year follow-up visit

For a smaller cohort of patients, the following events will take place in addition to the standard of care which would be received.
1. Demographic information and medical history will be recorded before surgery
2. CT scans of the hip will be performed post-operatively, at 2 days, 6 weeks, 3 months, 6 months, 9 months, 1 year and 2 years. The CT scan at 6 weeks will replace the X-ray that would normally have been given in routine care.
3. X-rays of the hip will be taken post-operatively 3 years, 5 years and 10 years.
4. Pre-operatively, and post-operatively at 6 weeks, 3 months, 6 months, 9 months, and annually up to 10 years, participants will be asked to complete questionnaires (EQ5D, Oxford Hip Score and Imperial Score) to evaluate hip function (these can be complete onsite or at participants own convenience). In addition, participants will be asked to complete a paper-based questionnaire (Harris Hip Score).
5. All participants will be followed up for 10 years and a final evaluation will occur at the end of the 10-year follow-up visit

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
H1 Hip Resurfacing Arthroplasty

Primary outcome(s)
1. The efficacy of the implant shall be measured by Implant survivorship (defined as 98.6% cumulative survivorship without revision for any reason at 1 year, 97.6% survivorship at 3 years, 96.5% survivorship at 5 years and 93% survivorship at 10 years)
At 6 weeks, 6 months, 1 year, 2 years, 3 years, 5 years, 7 years and 10 years:
2. Hip function will be measured by the Oxford Hip Score and the Imperial Hip Score
3. Quality of life shall be measured by the EQ5D score
4. Mobility and hip function shall be measured by the Harris Hip Score
5. Implant orientation and stability shall be measured by X-rays

Key secondary outcome(s)
1. Safety of the implant shall be measured by the number of adverse events and revisions throughout the study taken from patient records
2. Safety of the implant in terms of toxicology shall be measured by blood metal ion levels and compared to MHRA action levels using blood tests (when taken) at 3, 6, 12 and 24 months
3. Implant stability in terms of migration shall be measured by CT assessment at 6 weeks, 3, 6, 9, 12 and 24 months

Completion date
26/09/2032

Eligibility

Key inclusion criteria
1. Patient requires primary hip arthroplasty due to degenerative joint disease (primary osteoarthritis, posttraumatic osteoarthritis, avascular necrosis, developmental hip dysplasia)
2. Patients femoral bone stock is adequate for hip resurfacing on plain radiographs
3. Patient is between 18 and 70 years old
4. Patient willing to comply with study requirements
5. Patient plans to be available through 10 years postoperative follow-up
6. Patient is able to understand the native language of the country where their procedure is taking place.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Patient has a BMI greater than 40 kg/m²
2. Patient suffers from an active inflammatory joint disorder
3. Patient has an active infection or sepsis (treated or untreated)
4. Patient has insufficient bone stock at the hip (>1/3 necrosis of the femoral head)
5. Patient has severe osteopenia or osteoporosis, defined using DXA by T-score of <-2.5 (if T-score does not meet the criteria, please confirm with coordinating site (ICL) for participant eligibility)
6. Patient has large and multiple cysts in the femoral head (patients with cysts to be reviewed by coordinating site (ICL) for participant eligibility)
7. At the time of enrolment, patient has one or more of the following arthroplasties that have been implanted less than 6 months before the current hip arthroplasty:
7.1. Contralateral primary total hip arthroplasty or hip resurfacing arthroplasty
7.2. Ipsilateral or contralateral primary total knee or unicondylar knee arthroplasty
8. Patient takes medications which potentially affect the bone such as corticosteroids and antimitotic medications
9. Patient has a condition that may interfere with the hip arthroplasty survival or outcome (i.e., Paget's or Charcot's disease, vascular insufficiency, muscular atrophy, uncontrolled diabetes, moderate to severe renal insufficiency or neuromuscular disease)
10. Patient has a known alcohol or drug abuse
11. Patient has an immunosuppressive disorder
12. Patient has a malignant tumour, metastatic, or neoplastic disease
13. Patient has severe comorbidities or a limited life expectancy
14. Patient lacks capacity to consent
15. Patient has an emotional or neurological condition that would pre-empt his/her ability or willingness to participate in the study

16. Patient is not willing or able to sign an informed consent form
17. Patient pregnant or breast feeding
18. Patient is not able or willing to come to follow-up visits
19. Any other clinical reason, which the investigator considers would make the patient unsuitable for the trial
20. Implant size unavailable

Date of first enrolment
26/09/2017

Date of final enrolment
31/03/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Charing Cross Hospital
Fulham Palace Road
London
United Kingdom
W6 8RF

Study participating centre
King Edward VII Hospital
5-10 Beaumont Street
London
United Kingdom
W1G 6AA

Study participating centre
Epsom Orthopaedic Cente
Dorking Road
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United Kingdom
KT18 7EG

Study participating centre

Royal Cornwall Hospital
Treliske
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TR1 3LJ

Study participating centre
University College Hospital
235 Euston Rd
Bloomsbury
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NW1 2BU

Sponsor information

Organisation
Embody Orthopaedic Limited

ROR
https://ror.org/018caxa54

Funder(s)

Funder type
Industry

Funder Name
Embody Orthopaedic Limited

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be 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?

HRA research summary			28/06/2023	No	No
Participant information sheet	version v2	05/10/2020	04/01/2021	No	Yes
Protocol file	version v8	02/10/2020	04/01/2021	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes