

# Ceramic hip resurfacing vs total hip replacement

<b>Submission date</b> 11/12/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 04/01/2024	<b>Overall study status</b> Ongoing	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 17/06/2024	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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
2. Professor Justin Cobb, j.cobb@imperial.ac.uk

## Contact information

### Type(s)

Scientific

### Contact name

Dr Mariam Al-Laith

### Contact details

MSK Lab  
Sir Michael Uren Hub  
Imperial College London  
White City Campus  
86 Wood Lane  
London  
United Kingdom  
W12 0BZ  
+44 (0)2075942697  
m.al-laith@imperial.ac.uk

### Type(s)

Public

### Contact name

Ms Brogan Guest

### Contact details

MSk Lab  
Sir Michael Uren Hub  
Imperial College London  
White City Campus  
86 Wood Lane  
London  
United Kingdom  
W12 0BZ  
+44 (0)2075942697  
b.guest@imperial.ac.uk

### Type(s)

Principal Investigator

**Contact name**

Prof Justin Cobb

**ORCID ID**

<http://orcid.org/0000-0002-6095-8822>

**Contact details**

MSk Lab  
Sir Michael Uren Hub  
Imperial College London  
White City Campus  
86 Wood Lane  
London  
United Kingdom  
W12 0BZ  
+44 (0)2075945534  
[j.cobb@imperial.ac.uk](mailto:j.cobb@imperial.ac.uk)

## 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/m<sup>2</sup>
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

London

United Kingdom

W6 8RF

**Sponsor information****Organisation**

Embody Orthopaedic

**Sponsor details**

Sir Michael Uren Hub  
86 Wood Lane  
London  
England  
United Kingdom  
W12 0BZ  
+44 (0)2075943600  
camilla.halewood@embody-ortho.com

**Sponsor type**

Industry

**Website**

<https://www.embody-ortho.com>

**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?
<a href="#">Statistical Analysis Plan</a>	version 1.01	29/01/2024	17/06/2024	No	No