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Comparing the clinical and cost-effectiveness of robotic assisted total hip replacement to conventional total hip replacement in the management of adults with osteoarthritis of the hip

Submission date
06/05/2021

Recruitment status
No longer recruiting

Registration date
07/05/2021

Overall study status
Ongoing

Last Edited
19/10/2023

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoarthritis is a condition that causes joints to become painful and stiff. Hip replacement for hip osetoarthritis is usually very successful, however, some patients continue to have pain and cannot return to normal activities.
Robotic systems are being used increasingly to help perform this operation, but we do not know if they improve outcomes for patients. Some people think that robots help to fit the new hip joint with more precision which could improve outcomes. Using robotic systems cost more money, but this might be worth it if they provide better outcomes for patients.
We want to find out if:
1. Robotic assisted hip replacement gives better results for patients compared to non-robotic hip replacement.
2. Robotic assisted hip replacement good value for money for the NHS when compared to non-robotic hip replacement.

Who can participate?
Patients with osteoarthritis of the hip with pain, disability and radiological changes that, in the opinion of the treating clinician, warrants a total hip replacement.

What does the study involve?
Participants will be asked to answer short questionnaires about their hip and their general well-being. On the day of the operation, a computer will randomly decide whether the participant will have their hip replacement performed with or without robotic assistance.
Participants will be asked about their level of pain in the three days following surgery. We will calculate blood loss, record painkillers used and time spent in hospital. Questionnaires will be sent to participants at 6 weeks, 3, 6 and 12 months, 2, 5 and 10 years post-surgery to understand participants health relayed quality of life and record any problems with the hip replacement.

What are the possible benefits and risks of participating?
There are no specific benefits to taking part in the trial, except that participation would enable us to improve the care for patients needing a total hip replacement in the future and find out if the robotic assisted surgery is good value for money for the NHS.
There are general risks with any operation, but these would be present if the patient was having their treatment outside of the trial. The additional risk to taking part in the study is small. The pins which are used for the robotic system could rarely cause a fracture of the bone or an infection, but this is thought to be rare (less than one in every 1,000 cases). The additional radiation dose from the CT scans and X-Rays in the study is also very low risk, equivalent to around four years and seven months of background radiation. The risk associated with these examinations has been calculated at around 0.05% over an individual's lifetime. For comparison, the natural risk is 50% over an individual's lifetime.

Where is the study run from?
Royal Orthopaedic Hospital (UK)

When is the study starting and how long is it expected to run for?
May 2021 to June 2033

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

Who is the main contact?
Mr Peter Wall, racer-hip@warwick.ac.uk

Study website
http://www.warwick.ac.uk/racer-hip

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
295831

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
HTA - NIHR131407, IRAS 295831

Study information

Scientific Title
Robotic Arthroplasty: a Clinical and cost Effectiveness Randomised controlled trial for Hips

Acronym
RACER-Hip

Study objectives
Although total hip replacement can be very successful, many people have some persisting pain or functional restriction in the long term following the surgery. Robotic assisted hip replacement is thought to provide more precise and consistent surgical techniques and component position and therefor could reduce long term problems for patients undergoing this operation. However, this treatment comes at an additional cost, with no evidence that it is clinically superior to conventional total hip replacement surgery. This study will aim to assess the clinical and cost-effectiveness of robotic-assisted total hip replacement in comparison to conventional total hip replacement in adults undergoing this procedure for osteoarthritis of the hip.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomized multi-centre patient and assessor-blinded controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
http://www.warwick.ac.uk/racer-hip

Health condition(s) or problem(s) studied
Adults with osteoarthritis of the hip joint for which, in the opinion of the treating clinician, warrants a total hip replacement.

Interventions
Conventional total hip replacement and robotic-assisted total hip replacement, using the Mako Robotic system (Stryker, USA)

Randomisation will be completed using a secure online web system and will be performed on the day of surgery. Both treatment arms will receive additional scans in the form of a pre-operative CT scan and up to three pre-operative X-Rays, as well as a post-operative CT scan 3 months after surgery.

The participants who are allocated to the robotic assisted surgery group will undergo surgery using the Stryker Mako robotic arm system, using Stryker implant constructs. This can either be hybrid or cemented construct. In order to use the Mako surgical robot, three marker pins are required to be placed around the hip to enable the robot system to orientate the anatomy of the hip joint. The result of this is three additional incisions where the markers pins have been placed.

The participants who are allocated to the conventional total hip replacement will be delivered using conventional instruments and the same Stryker implants, using either a hybrid or cemented construct. The implant construct will be confirmed prior to randomisation to ensure the same implants would be used in both intervention and control groups. In order to keep the allocation blinded, the conventional hip replacement group will receive three small sham incisions where the marker pins would have been placed.

All other care, including the choice of anaesthetic and post-operative analgesia will be according to usual care. The rehabilitation programme will be standardised between groups, but this is expected to be consistent with usual practice across all sites.

Intervention Type
Procedure/Surgery

Primary outcome measure
Joint awareness measured using the Forgotten Joint Score Hip-12 (FJS-12) at 12 months post-surgery

Secondary outcome measures
Peri-operative outcomes:
1. Mean pain intensity, using an 11-point numerical rating scale for "pain right now" and "pain since yesterday" on the morning of each of the first three days following surgery and at baseline
2. Estimated blood loss calculated using Brecher's formula, based on pre- and post-operative Haematocrit measurements from routinely collected clinical blood measurements, and volume, if any, of blood transfused
3. Opioid use to the end of day three measured using patient records
4. Hours from surgery to hospital discharge measured using patient records

Outcomes collected at baseline, three and six months and one, two, five and ten years post-operation:
1. Overall hip pain and function measured using FJS-12
2. Overall hip pain and function measured using Oxford Hip Score
3. Health utility measured using EQ-5D-5L (also collected at 6 weeks)
4. Satisfaction with total hip replacement, measured using a five-point Likert scale
5. Resource use using patient questionnaires
6. Re-operations

Process and Fidelity measures:
1. Time from skin incision to final dressing measured using patient records
2. Alignment measures at three months on a focused low-dose CT: rotation of femoral and acetabular components, leg length and offset compared to pre-operative plan

Safety outcomes:
1. Adverse events relating to the operation, the anaesthetic or rehabilitation measured using patient records

Overall study start date
06/05/2021

Completion date
30/06/2033

Eligibility

Key inclusion criteria
1. Osteoarthritis of the hip with pain, disability and radiological changes that, in the opinion of the treating clinician, warrants a total hip replacement
2. Conservative therapy has been unsuccessful, as judged by the treating clinician

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
378

Key exclusion criteria
1. Osteoarthritis due to inflammatory arthropathy or intra-articular fracture, as judged by the treating clinician
2. Revision surgery or need for complex implants, or any other implant than a standard hybrid

construct (Trident Exeter) or uncemented construct (Trident Accolade), as determined by the treating clinician. This includes nickel-free implants as well as those that require a long stem, augments, or custom made devices
3. Age < 18 years
4. Unfit for THR, or surgery is otherwise contra-indicated, for example, concurrent infection
5. Previous randomisation in the present trial, i.e. the other hip
6. Unable to take part or adhere to trial processes including prisoners or people unable to communicate or complete questionnaires in English, or people unable to give informed consent

Date of first enrolment
01/10/2021

Date of final enrolment
30/09/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Orthopaedic Hospital
The Woodlands
Bristol Road South
Northfield
Birmingham
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B31 2AP

Sponsor information

Organisation
University Hospitals Coventry and Warwickshire NHS Trust

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Sponsor type

Hospital/treatment centre

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Sponsor type
University/education

Website
http://www2.warwick.ac.uk/

ROR
https://ror.org/01a77tt86

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
The results of the trial will be reported first to trial collaborators. The main report will be drafted by the trial coordinating team, and the final version will be agreed by the TSC before submission for publication (and NIHR prior to publication), on behalf of the collaboration.
The trial management team and other collaborators will prepare the study monograph within the agreed timetable, which will start to be prepared at the end of recruitment, ensuring that the results of the analysis can be inserted into a well-prepared document and reducing the time to prepare the final report after the analysis.
The trial will be reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines (https://www.consort-statement.org).

Intention to publish date
30/06/2034

Individual participant data (IPD) sharing plan
Any datasets generated will be available upon request from WCTU Data Sharing Committee (DSC) (WCTUDataAccess@warwick.ac.uk). De-identified data will be available for non-commercial use, up to one year after the publication of the trial results, or from metadata stored in a university repository for up to ten years without investigator support. To access trial data, third parties must complete a data-sharing agreement, have an ethically approved protocol in place, and agree to the approved protocol with the WCTU DSC. Data may be used for commercial purposes, according to the conditions above, but will need additional agreements in place, which may include a license fee. Available data will include (but is not exclusive to) de-identified individual participant data, the study protocol, the statistical analysis plan, informed consent sheets and analytic codes.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.2	30/06/2021	03/05/2023	No	Yes
Protocol (other)	v1.1	22/06/2021	03/05/2023	No	No
Protocol file	version 1.1	22/06/2021	03/05/2023	No	No
Protocol article		18/10/2023	19/10/2023	Yes	No