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Patient reported clinical outcomes and imaging study for a new all-ceramic hip resurfacing device

Submission date
05/10/2020

Recruitment status
No longer recruiting

Registration date
15/10/2020

Overall study status
Ongoing

Last Edited
12/12/2024

Condition category
Musculoskeletal Diseases

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

Plain English Summary
Background and study aims
Hip replacement is a successful medical intervention that treats diseased or damaged joints. There are two options for hip replacement implants and this is total hip replacement or hip resurfacing replacement. A total hip replacement removes the entire head of the bone for replacement whereas hip resurfacing as it suggests removes just the damaged surface of the joint. Hip resurfacing is therefore a more bone-conserving operation and may offer benefits to younger/active patients.
Currently hip resurfacing is manufactured using all-metal (cobalt chromium). A small proportion of patients can have an adverse reaction to metal debris leading to early failure of the implant. Therefore more benign materials such as ceramics commonly used in total hip replacement are of interest and BIOLOX® delta ceramic (CeramTec) has clinical use. MatOrtho's ReCerf is an all-ceramic hip resurfacing device manufactured from this clinically successful BIOLOX® delta ceramic. The aim of this study is to demonstrate the performance of ReCerf Hip Resurfacing is comparable to clinical data from existing hip implants and this data will support regulatory applications in the future.

Who can participate?
Adults eligible for hip resurfacing.

What does the study involve?
All patients would complete questionnaires about their hip before surgery and then at 6, 12 and 24 months post-surgery. Adverse events and revision would be reported over 24 months. Standard radiographs would be collected. Patients recruited at Oxford would be assessed by RSA after surgery (within 5 days) and at 6, 12 and 24 months post-surgery.

What are the possible benefits and risks of participating?
Benefits:
The information collected in this programme will be used to increase medical community knowledge on Hip Resurfacing implants. This could influence future thinking on the best treatment routes. The Hip Resurfacing itself should provide the patient with relief from their

symptoms. Collecting data does not intervene in any way with the patients normal treatment and rehabilitation programme.

Risks:
There are general risks of surgery and receiving a hip implant. There are risks to receiving a new device. The clinical performance and longevity of the ReCerf device are not proven and residual risks are possible. Unknown or unexpected failure modes can occur for new devices.
X-rays used to assess the positioning of a hip replacement expose you to a small amount of radiation.
Patients taking part in RSA migration study will have very small tantalum beads placed in the bone near to the Investigational Device. The insertion of beads takes an additional 5 to 10 minutes during surgery. Although this increases surgical time, there is no increase incidence of infection, bleeding, or blood clotting. The beads get stably integrated into the bone, however, the beads could move or become loose, eventually embedding in adjacent tissue. This risk is considered very small; over 300,000 beads have been implanted worldwide with no adverse effects related to bead movement or loosening.

Where is the study run from?
MatOrtho Limited (UK) and hospitals in the UK

When is the study starting and how long is it expected to run for?
June 2019 to April 2027

Who is funding the study?
MatOrtho Limited (UK)

Who is the main contact?
MatOrtho Limited, info@matortho.com
Andrew Manktelow, Nottingham University Hospital Trust
James Holland, Freeman Hospital, Newcastle Upon Tyne Hospital Trust
Sarah Muirhead-Allwood, Princess Grace Hospital
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Contact information

Type(s)
Scientific

Contact name
Dr Study Contact

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
277975

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ST-010320-CI, IRAS 277975

Study information

Scientific Title
ReCerf Hip Resurfacing Clinical Investigation

Study hypothesis
There are two hypotheses: The clinical trial will assess that the amount of migration of components over time as compared to the surrounding bone (reference) is acceptable; and patient reported outcome using an Oxford Hip Score questionnaire will not be worse than the National average reported in the UK National Joint Registry for similar devices.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/04/2020, London-Stanmore Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)20 7972 2561, stanmore.rec@hra.nhs.uk), ref: 20/LO/0279

Study design
Prospective observational non-randomized multicentre

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Condition
End-stage joint disease e.g. osteoarthritis, requiring hip joint replacement

Interventions
All patients taking part in the study would receive a Patient Information Sheet from their consultant if they are eligible for hip resurfacing. Following consent the patient would be asked to answer a series of questionnaires on their hip (baseline, pre-op data). Information on pre-op health and demographics would be recorded prior to surgery. The data collected would not include personal information and would not identify the patient. The patient would only be identified with the study ID number throughout. Intra-operatively, surgical details would be collected including component details. Post-operatively patients would complete questionnaires at 6, 12 and 24 months. Standard radiographs would be taken and collected for the study. Throughout, adverse events including readmissions and revisions would be collected.

In addition, patients recruited at Oxford would be invited to take part in a migration ('RSA') study. The patients would complete all of the same methods above but would also have RSA imaging. RSA stands for radiostereometric analysis and it is a highly accurate method to measure small movements over time between the implant components and the bone. RSA uses a dual set of stereo x-rays. The RSA assessment is taken immediately post-surgery (within 5 days) and at 6, 12 and 24 months.

The total duration of follow-up for all patients is 24 months post-surgery. The observations will take around 20-30 minutes for patient reported scores. The RSA assessment would take 40-60 minutes.

Intervention Type
Device

Phase
Not Specified

Drug/device/biological/vaccine name(s)
ReCerf Hip Resurfacing

Primary outcome measure
1. Proximal migration measured by RSA at 12 months
2. Hip function measured using the Oxford Hip Score at 6 months

Secondary outcome measures
1. Migration measured by RSA at 6 and 24 months
2. Hip function measured using the Oxford Hip Score at 12 and 24 months
3. Rate of adverse events collected by research team as they occur (all times to 24 month)
4. Revision rate (i.e device failure rate) measured by research team as they occur (all times to 24 month)
5. Additional PROMs (pre-op, 6, 12 and 24 months):
5.1. Hip function (Oxford Hip Score)
5.2. Quality of life (EQ5D)
5.3. Hip symptoms (HOOS)

5.4. Activity (UCLA Activity Scale)
5.5. Satisfaction score (using a novel 4 item questionnaire)
5.6. Single question on joint awareness

Overall study start date
06/06/2019

Overall study end date
30/04/2027

Eligibility

Participant inclusion criteria
1. Patient suitable for hip resurfacing arthroplasty
2. Patient able to give informed consent
3. Patient willing and able to take part in the study for the prescribed length of the study
4. Willing to allow his or her General Practitioner and consultant, if appropriate, to be notified of participation in the study
5. Minimum age of 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
78

Participant exclusion criteria
1. Patient deemed unsuitable for hip resurfacing arthroplasty by the surgeon
2. Patient has significant contraindications when following the manufacturer's Instruction For Use of the product
3. Patient likely to become incapacitated during the study
4. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the study, or may influence the result of the study, or the participant’s ability to participate in the study

Recruitment start date
30/06/2020

Recruitment end date
31/03/2025

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Freeman Hospital
James Holland
Newcastle Upon Tyne Hospital Trust
Freeman Road
High Heaton
Newcastle
United Kingdom
NE7 7DN

Sponsor information

Organisation
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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
MatOrtho Limited

Results and Publications

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

Intention to publish date
31/01/2028

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No