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Randomised controlled trial to assess an all-polyethylene tibia medial rotation knee implant compared to a metal-backed tibia implant

Submission date
17/12/2014

Recruitment status
No longer recruiting

Registration date
15/04/2015

Overall study status
Completed

Last Edited
18/12/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Total knee replacement has been performed for over 40 years as last resort treatment of arthritis and damaged knee joints. A knee replacement aims to reduce pain, stiffness and immobility. The most common measures of success in joint replacement surgery to date has been the rate at which a revision is required (further surgery to replace worn out components etc). The success of an implant can also be determined using validated patient reported outcome measures (PROMs) which are defined as validated measures to assess any aspect of health which come from the patient themselves.
The Medial Rotation Knee (MRK) from MatOrtho Limited is a total knee replacement system that was CE marked in 1994. It has proven to be a very successful design of knee replacement and shows the best revision rates at only 1.83% in 7 years from the UK. This study will compare two types of knee replacement implants (all-polyethylene tibia medial rotation knee implant vs metal-backed tibial medial rotation knee).

Who can participate?
Adult patients undergoing total knee arthroplasty for any indication.

What does the study involve?
Participants will be allocated to one of the two groups: 75 will receive metal-backed MRK implants and 75 will receive all-polyethylene tibia MRK implants. They will then be followed up over a 2 year period, during which they will be asked to complete various PROMs questionnaires, before and after the operation.

What are the possible benefits and risks of participating?
Taking part in the study will not impose any further risks on to the patient. The patients will be asked to attend an extra follow up appointment 2 years post-operatively and travel expenses will be offered to the patients to minimise any inconvenience. The potential risks of the surgery will remain the same regardless of whether the patient takes part or not, this will be fully explained to the patient during the consent process.

Where is the study run from?
The study is run by the Robert Jones & Agnes Hunt Orthopaedic Hospital NHS Foundation Trust and he patients will be recruited from 3 NHS sites across the UK.

When is the study starting and how long is it expected to run for?
July 2014 to December 2018 (updated 03/07/2019, previously: July 2018)

Who is funding the study?
MatOrtho Ltd.

Who is the main contact?
Dr Catherine Whitall
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Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number
164614

ClinicalTrials.gov number

Secondary identifying numbers
MOP0001, IRAS 164614

Study information

Scientific Title
Medial Rotation Knee Randomised Controlled Trial Allpolyethylene versus Metal backed tibia

Acronym
MRK Poly Vs Metal

Study objectives
There is no difference in range of motion between the all-polyethylene tibia and metal-backed tibial medial rotation knee implants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Greater Manchester South, 26/02/2015, ref: 15/NW/0005

Study design
Multi-centre randomised controlled imterventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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

Health condition(s) or problem(s) studied
Patients undergoing total knee arthroplasty for any indication.

Interventions

Participants in the study will all be undergoing total knee arthroplasty, group A will receive the all-polyethylene tibia medial rotation knee implant whereas group B will receive the metal-backed tibial medial rotation knee.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Medial Rotation Total Knee Replacement

Primary outcome measure
Compare the mean range of motion (ROM) of the all-polyethylene tibia MRK to the metal-backed tibia MRK. A difference of means in ROM of 5 degrees or more will be used to determine if there is a difference in the clinical outcome of the all-polyethylene tibia and the metal-backed tibia.

Secondary outcome measures
Patient reported outcome measures will be compared for the two treatment arms, including the Oxford Knee Score, the EQ-5D, Modified Forgotten Joint Score, and the UCLA Activity score.

Overall study start date
22/07/2014

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Primary total knee arthroplasty (for any indication)
2. Informed consent to participate in the study provided by the patient
3. Patients aged over 18 years
4. Able to understand and respond to Patient-reported outcome measures (PROMs) for the duration of the study period

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Total final enrolment
162

Key exclusion criteria
1. Severe muscular, neurological or vascular deficiencies which compromise the affected extremity
2. Bone deficiency or deficient bone quality likely to compromise the implant (as determined by surgical team on pre-operative radiographs)
3. Severe ligament instability
4. Hypersensitivity to the materials used
5. Alcoholism or other addictive disorders
6. Sepsis
7. Osteomyelitis
8. Osteomalacia
9. Severe osteoporosis – clinical judgement
10. Metabolic disorders which may impair bone formation
11. Patients lacking capacity to provide consent
12. Those whose prospects for a recovery to independent mobility would be compromised by known pre-existing medical conditions
13. Patients who have their contralateral knee already in the study

Date of first enrolment
09/04/2015

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Robert Jones & Agnes Hunt Orthopaedic Hospital NHS Foundation Trust
Oswestry
Shropshire
United Kingdom
SY10 7AG

Sponsor information

Organisation
MatOrtho Limited

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Sponsor type
Industry

Website
www.matortho.com

Funder(s)

Funder type
Industry

Funder Name
MatOrtho Limited

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 24/08/2023:
Target 2024

Previous publication and dissemination plan:
To be confirmed at a later date

Intention to publish date
01/07/2025

Individual participant data (IPD) sharing plan
Current individual participant data (IPD) sharing plan as of 24/08/2023:
The datasets generated during and/or analysed during the current study are not expected to be made available

Previous individual participant data (IPD) sharing plan:
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary

Not expected to be made available

Study outputs

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