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A comparison between robotic and orthosensor-assisted total knee replacement and standard total knee replacement surgery

Submission date
25/11/2019

Recruitment status
Suspended

Registration date
10/01/2020

Overall study status
Completed

Last Edited
24/01/2022

Condition category
Musculoskeletal Diseases

[ ] 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
Total knee replacement is one of the most commonly performed surgical procedures with over 100,000 carried out in the UK each year. It is well known that 10-20 % of patients undergoing knee replacement are dissatisfied with the outcome of their surgery. Patients complain of ongoing pain and instability, with a proportion needing further surgeries to revise the knee replacement.
There is no agreed explanation as to why there is such a large variation in satisfaction after knee replacement. It is acknowledged that the knee implant is not ideally positioned in up to 30% of standard knee replacement surgeries. We do not know how the positioning of the implant affects the patient's outcome following surgery.
Robotic-assisted surgery is a technique used by orthopaedic surgeons to ensure the implant is more accurately positioned during surgery. Although we know that this technique results in increased accuracy in positioning of the implant, we do not know if this would result in better outcomes for patients following their knee replacement.
The aim of the research study to see if a better outcome is achieved using robotic-assisted surgery compared to standard surgery.

Who can participate?
Patients age 45 – 85 years, listed for elective primary TKR for end-stage osteoarthritis, and suitable for a cruciate retaining TKR (Triathlon prosthesis).

What does the study involve?
Participants will be randomly allocated to have their knee replacement performed using the standard technique; or have their knee replacement performed using robotic-assisted surgery to optimise the position of the knee implant. Information will be collected on participants recovery from surgery as well as their knee function, pain, satisfaction, and walking, up until 12 months after their knee replacement to see if one group does better than the other.

What are the possible benefits and risks of participating?
Benefits: The information we get from this trial will inform future practice and will benefit

future patients.
Risks: The risks for the two groups are the same as those for any knee replacement surgery. In addition, it is anticipated that those patients with patients who are randomised to use of the robotic instrumentation may require a longer procedure of up to 20 minutes, and there is a theoretical increased risk of infection. There is also a small (1%) risk of sustaining a fracture through a tracker pin (a threaded pin inserted into the bone so the robot can establish the position of the bone in time and place). Participants may have CT of the hips, knees and ankles. These will be additional to standard care Xrays of the knees. These procedures use ionising radiation to form images of the body which will be used for planning the surgery. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous. The normal risk of anyone developing cancer during their lifetime is about 50%. By taking part in this study this risk becomes an estimated 50.02%.

Where is the study run from?
Freeman Hospital, UK

When is the study starting and how long is it expected to run for?
May 2019 to December 2021

Who is funding the study?
The research is funded by Stryker who make knee replacements and the MAKO robotic arm used in surgery.

Who is the main contact?
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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
247437

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 40324, IRAS 247437

Study information

Scientific Title
Robotic and Orthosensor Assisted versus Manual (ROAM) total knee replacement: A randomised controlled trial

Acronym
ROAM

Study objectives
An optimally aligned and balanced TKR carried out with robotic-assisted surgery and the use of the Orthosensor improves patient outcomes when compared to a TKR carried out manually.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/02/2019, North East - Tyne and Wear South Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44(0)207 1048084; nrescommittee.northeast-tyneandwearsouth@nhs.net), ref: 19/NE/0027

Study design
Randomized; Both; Design type: Treatment, Surgery, Case-controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Arthrosis of knee

Interventions
A randomised controlled trial will be conducted to compare the outcomes of patients undergoing a conventional manual knee replacement to those undergoing TKR using robotic assisted surgery and the Orthosensor to optimise alignment and balance the knee joint respectively and assess the associated cost economics of such technology.

The null hypothesis is that an optimally aligned and balanced TKR carried out with robotic assisted surgery and the use of the Orthosensor does not improve patient outcomes when compared to a TKR carried out manually.

Informed Consent
Written and verbal versions of the Participant Information Sheet and Informed Consent Form will be presented to the participants by the research team. These will explain the exact nature of the study, the implications and constraints of the protocol and any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, and with no obligation to give the reason for withdrawal.

The participant will be encouraged to take the study information home and have the opportunity to question the Investigator, their GP or other independent parties to decide whether they will participate in the study.

Participants who decide to take part will be invited to an additional research visit to provide written informed consent. The person who obtained the consent will be a suitably qualified and experienced member of the research team, and have been authorised to do so by the Chief /Principal Investigator.
Copies of the signed Informed Consent will be given to the participants as well as filed in the medical notes.

Participants will be randomly allocated 1:1 to either standard care or the intervention group. Participants randomised to standard care will undergo a conventional manual TKR. Participants randomised to the intervention group will undergo a TKR with the assistance of the MAKO robot and the use of orthosensors to optimise the balance and alignment of the TKR.

Participants will be followed up at routine clinic appointments at 8 weeks and 12 months post op with an additional research visit at 6 months post op – this visit can be done face-to-face or via postal questionnaires. After the 12 month follow up the participants will continue with the institutions standard
post-operative care.

Research Assessments

Additional Research visit
Participants will be asked to attend a research appointment to provide written informed consent, complete a CRF and a number of pre-operative questionnaires recording their knee function, expectations and general health. Participants will be asked to complete a short assessment of their gait and balance. After completing the baseline assessments participants will be randomised to one of two groups. Patients will be informed of their allocation and arrange a CT for those randomised to the intervention group.

Admission for surgery
Taking part in the study will not affect waiting time for surgery. Participants will be admitted and receive the same standard of care during their hospital stay. Participants will undergo either a standard knee replacement or the robotic assisted knee replacement. In both cases participants will receive the same implant.
For participants allocated to the group undergoing robotic assisted surgery the data from their CT scan will be used to plan the surgery. A MAKO technician will be present during all surgical procedures to ensure technical issues, should they arise, are addressed immediately. It may take

up to 20 minutes longer to complete the knee replacement surgery using the robot compared to the standard manual TKR.

Routine Follow up visits
Participants will be expected to attend routine clinical follow up appointments at 8 weeks and 12 months following their surgery. At this point participants will be asked to complete the same questionnaires about their knee function and general health. In addition they will complete questionnaires about satisfaction and any healthcare visits associated with the knee replacement since their previous visit.

Additional Research Review
At the 6 month time point, participants will be asked to complete the same questionnaires as the 8 week and 12 month visit. This can be done face-to-face, via post or telephone call according to patient preference.

Each of the visits outlined above are essential to the successful completion of this study. If participants are already aware of any reason that they will not be able to attend these visits then they will not be able to participate in this study.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Early functional outcome (measured by the WOMAC) from baseline to 6 months following TKR

Key secondary outcome(s))
1. Knee function in activities of daily living measured by the Oxford Knee Score (OKS) from baseline to 8 weeks, 6 and 12 months
2. Joint awareness measured by the Forgotten Joint Score (FJS) from baseline to 8 weeks, 6 and 12 months
3. Satisfaction after total knee replacement measured using a validated outcome measure at 8 weeks, 6 and 12 months
4. Pain, stiffness and functional ability measured using components of the WOMAC at 8 weeks, 6 and 12 months and function at 8 weeks and 12 months
5. Health-related quality of life measured using the EQ-5D-3L at baseline, 8 weeks, 6 and 12 months
6. Cost-effectiveness of the two interventions from a UK NHS perspective measured using a health service resource use questionnaire will be completed by the patient at the 8 weeks, 6 and 12 month post-surgical research assessment. Inpatient and surgical data will be collected on the case report forms (CRF's) and complications will be recorded at each visit. The tariffs associated with surgery, in-patient stay, follow up visits and any treatment for complications will be retrieved from hospital finance records at the end of the follow up period
7. Gait patterns and balance (centre of pressure excursion) will be measured using a TekScan instrumented walkway over which patients walk and stand. Activity levels will be monitored in a sub-set of patients using ActivPal activity monitors. Gait/balance/activity will be monitored pre-surgery and at 12 months post-surgery.

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Listed for elective primary TKR for end stage osteoarthritis under the care of the two participating surgeons
2. Male or female, age 45 – 85 at the time of listing for surgery
3. Suitable candidate for a cruciate retaining TKR (Triathlon prosthesis)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Incompetent MCL (grade III in laxity) observed by consultant on examination
2. Unable to comply with the study protocol (incl. refusal for CT scan)
3. Pregnant, lactating or planning pregnancy during the course of the study
4. Requires patella resurfacing
5. 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

Date of first enrolment
09/05/2019

Date of final enrolment
30/06/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Industry

Funder Name
Stryker

Alternative Name(s)
Stryker Corporation, Orthopedic Frame Company

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

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

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?
Protocol article		22/02/2022	24/01/2022	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes