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A comparison of standard versus robotic total knee replacement

Submission date
30/06/2020

Recruitment status
No longer recruiting

Registration date
08/07/2020

Overall study status
Ongoing

Last Edited
12/02/2024

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
Knee arthritis is a painful condition which can limit people's activities. When knee arthritis is very bad, it can be treated with a knee replacement. These operations are often very successful at reducing pain and improving the amount of activity someone can do. They can be painful in the few weeks after the operation, and many people still have some knee symptoms, even some time after surgery.
Knee replacements have for many years been put in by surgeons using their experience and skill, with a standard set of instruments. However, some surgeons have started using a robotic arm to help them perform a knee replacement. The robotic arm is held by the surgeon during the operation and the surgeon always remains in control. The robot helps move the instruments into the correct position by sensing the position of the leg.
Those who believe that standard instruments are better think that the operation is quicker and simpler without the robot. They argue that they can make decisions and cut the bone with the same amount of precision and without the added expense of a robot. Whereas those who believe the robot is better think it makes them more precise, and that they can get a better result using the guidance provided by the robot.
No one yet knows if using the robot to help perform a knee replacement is any better or worse than performing a knee replacement with standard instruments. Therefore, this study will look at which operation is best at improving the way the knee feels after surgery. The study will also find out which operation results in less pain in the first few days after surgery, and which gives better quality of life in the long-term. The researchers will also study whether the use of the robot is worth the additional cost.

Who can participate?
People with knee osteoarthritis who are due to undergo total knee replacement

What does the study involve?
Participants will be randomly allocated (by an online system) to have a knee replacement performed using either standard instruments or the robotic system. This will be done on the day of surgery. The surgeon will not be able to influence this decision.
Before the operation, every participant will have a CT scan of their knee to make a plan to best fit the knee replacement. A short scan of the hip and ankle will also be performed. As part of the

study, a short CT scan of the knee and x-ray of the whole leg will also be undertaken 3 months after the operation. All other x-rays will be part of normal care.
For knee replacement with standard instruments, the surgeon will use their normal approach to perform a knee replacement and will be allowed to make whatever adjustments they think they need to get the best result for each participant. They will perform this using their usual instruments, as they would for any standard knee replacement, using the experience and skill they have built up in their clinical practice.
For knee replacement using the MAKO robotic system, the robotic system being tested is the Stryker MAKO system. This is the most widely used robotic knee replacement system at present. It has been used many thousands of times, in the UK and abroad, and it is safe. It has a CE mark and is licenced for use in the UK. The surgeon starts the operation and inserts some pins into the bone, at the top of the shin, often through two small (1 cm) incisions. The pins are used to show the computer where the bones are. The surgeon then performs the operation as usual, but instead of using their normal instruments, they use a robot to guide where they cut the bone, making whatever adjustments they think they need to get the best result. They will then insert the knee implants with cement in the normal way.
Participants having the standard operation will also have these two additional 1 cm incisions (even though they will not be used). This is to ensure that people in the study do not know which group they are in. These are very low risk and will not affect recovery.
On the day after the operation, and for the following 2 days, a member of staff will ask each participant about their knee pain. Each participant will also be given a discharge booklet (including advice and exercises) which explains what to do after the operation. If the surgical or physiotherapy team think extra physiotherapy is required, this will be organised.
Questionnaires that are used to assess joint awareness, pain, levels of activity, quality of life and satisfaction with the operation will be sent to participants at 6 weeks, 3, 6 and 12 months after surgery. The researchers will also send follow-up questionnaires 2, 5 and 10 years after the operation.

What are the possible benefits and risks of participating?
It is not known which type of knee replacement provides the best outcome for patients both physically and in terms of wellbeing. Nor is it known whether the robot is worth the additional cost. By taking part in the trial, participants are helping to decide about the best treatment for people in the future.
There are general risks with any operation. When having a knee replacement, it is normal to get some early pain, swelling, bruising and some drowsiness or sickness from painkillers. Numbness over the knee and some stiffness are also normal. Risks of having a knee replacement include continued or worse pain, infection, wound problems, stiffness, need for further surgery including redoing the knee replacement, blood clots in the leg or lung, death, or injury to structures around the knee such as nerves or vessels. The additional risk of taking part in the study is very small. The pins in the bone used by the robot could cause a fracture of the bone, but this is thought to be rare (less than one in every 1,000 cases). The radiation dose from the scans have also been calculated and are very low risk.

Where is the study run from?
University of Warwick (UK)

When is the study starting and how long is it expected to run for?
July 2018 to July 2024 (for completion of 12-month follow-up) and to March 2032 (for completion of long-term follow-up) (Updated from "July 2018 to July 2023 (for completion of 12-month follow-up) and to March 2032 (for completion of long-term follow-up)" in January 2023)

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

Who is the main contact?
Jeskaran Rai (Trial Manager)
RACER@warwick.ac.uk

Study website
https://warwick.ac.uk/fac/sci/med/research/ctu/trials/current/racer/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
278357

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
HTA - NIHR128768, V1.0, IRAS 278357

Study information

Scientific Title
Robotic Arthroplasty: a Clinical and cost Effectiveness Randomised controlled trial (RACER)

Acronym
RACER

Study objectives
To determine whether robotic total knee replacement (TKR) is clinically and cost-effective when compared to TKR using conventional instruments.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Submission pending, East Midlands - Nottingham 2 Research Ethics Committee (The Old Chapel Royal, Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8169, +44 (0)207 104 8035, +44 (0)207 104 8103; nottingham2.rec@hra.nhs.uk); REC ref: 20/EM/0159

Study design
Multi-centre patient-assessor blinded pragmatic randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
https://warwick.ac.uk/fac/sci/med/research/ctu/trials/racer/ab101informationforparticipants/racer_pis_v4.0_26nov2021.pdf

Health condition(s) or problem(s) studied
Osteoarthritis of the knee with pain, disability and changes on standard of care clinical images (x-rays or MRI according to normal clinical practice) that, in the opinion of the treating clinician, warrants total knee replacement (TKR)

Interventions
RACER is a multi-centre, patient-assessor blinded, pragmatic randomised controlled trial to assess the clinical and cost-effectiveness of robotic total knee replacement (TKR) compared to conventional TKR in the UK NHS health setting. This is the equivalent of a phase III study according to the IDEAL classification.

Participants will be randomly allocated (1:1) to the two treatment groups via a central computer-based randomisation system provided by the Warwick Clinical Trials Unit (WCTU, independent of the study team). This will be performed by minimisation with a random factor, with a 70% weighting towards balance across the whole study, stratified for age, hospital site, surgeon, BMI ≥35 at baseline, and primary compartment involved (medial, lateral or patellofemoral, as determined by the treating clinician).

A full summary of the intervention and control procedure will be available in an accompanying RACER surgical manual, prepared following a surgical consensus meeting to which all surgical co-investigators were invited.

The intervention treatment will be total knee replacement (TKR) performed using the MAKO robotic system and Triathlon (Stryker, USA) implants, the only implant compatible with the MAKO robot. All implants will be cemented (96% of TKRs recorded on the National Joint Registry (NJR) are cemented). No uncemented implants will be used.

Participants in both groups will have a CT scan according to the needs of the MAKO system (an imaging manual will be prepared, the CT also includes some imaging at hip and ankle) and a three-dimensional plan will be made for the surgeon, isolating the effect of the robot from surgical planning. This is done at least 2 weeks prior to surgery, but no more than 8 weeks before the planned date of surgery to ensure bone shape does not change due to disease progression.

The control treatment will be TKR delivered using conventional instruments, using the same Triathlon (Stryker, USA) implants as the intervention. The details of this procedure will also be documented in the RACER surgical manual. The Triathlon knee replacement is already commonly used in the UK, it is the third most common brand used in the NHS (94,800 recorded cases on the National Joint Registry since 2004). As in the intervention arm, all implants will be cemented.

Two or four small incisions will be used to blind to marker placement, these will be identical to the 1 cm incisions used for the robotic group and will be covered in the same small dressings. The RACER trial PPI group had no objection to this.

Total duration of follow-up: 10 years

Intervention Type
Device

Phase
Phase III

Drug/device/biological/vaccine name(s)
MAKO robotic system and Triathlon (Stryker, USA) implants

Primary outcome measure
Current primary outcome measure as of 06/01/2023:
Patient awareness of their joint measured using Forgotten Joint Score (FJS) questionnaire at 12 months post-randomisation

Previous primary outcome measure:
Patient awareness of their joint measured using Forgotten Joint Score (FJS) questionnaire at baseline, 3, 6, 12 months, 2, 5 and 10 years

Secondary outcome measures
Current secondary outcome measure as of 06/01/2023:
In-hospital outcomes:
1. Mean pain intensity measured using an 11-point numerical rating scale (NRS) questionnaire for

'pain right now' and 'pain since yesterday' on the morning of each of the first 3 days after surgery
2. In-patient estimated blood loss calculated using Brecher's formula, based on pre- and post-operative Haematocrit measurements obtained from reviewing patients notes post-discharge
3. In-patient opioid use obtained from patient's medical notes (total morphine equivalent, using conversion methods established in I-WOTCH, NIHR HTA 14/224/04) to the end of day 3
4. Hours from surgery to hospital discharge obtained from patient's medical notes post-discharge
5. Pain over the past 24 hours, when the operated knee is at rest and when it is moved, collected as above on the first three days.

Postoperative outcomes:
1. Overall knee function measured using the FJS at baseline, 3, 6, 12 months, 2, 5 and 10 years
2. Outcomes of knee osteoarthritis surgery measured using the Oxford Knee Score (OKS) questionnaire at baseline, 3, 6, 12 months, 2, 5 and 10 years
3. Levels of activity and (social) participation measured using the Oxford Knee Score Activity and Participation Questionnaire (OKS – APQ) at baseline, 3, 6, 12 months, 2, 5 and 10 years
4. Generic health status measured using the EQ5D-5L questionnaire at baseline, 6 weeks, 3, 6, 12 months, 2, 5 and 10 years
5. Pain over the last week measured using the three-item PROMIS Pain Intensity Scale questionnaire at baseline, 3, 6, 12 months, 2, 5 and 10 years
6. Satisfaction with the knee replacement measured using a five-point Likert scale questionnaire at 3, 6, 12 months, 2, 5 and 10 years
7. Activity limitations, symptoms, emotions, and overall quality of life-related to the painful condition assessed using a Participant Global Impression of Change questionnaire – a seven-point Likert scale – at 3, 6, 12 months, 2, 5 and 10 years
8. Number of re-operations measured using a single question - Have you had a re-operation or revision of your knee replacement – at 3, 6, 12 months, 2, 5 and 10 years
9. Number of episodes and type of NHS services the patient has used measured using resource use questionnaire at 3, 6, 12 months, 2, 5 and 10 years

Previous secondary outcome measure:
In-hospital outcomes:
1. Mean pain intensity measured using an 11-point numerical rating scale (NRS) questionnaire for 'pain right now' and 'pain since yesterday' on the morning of each of the first 3 days after surgery
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7. Number of re-operations measured using a single question - Have you had a re-operation or revision of your knee replacement – at 3, 6, 12 months, 2, 5 and 10 years
8. Number of episodes and type of NHS services the patient has used measured using resource use questionnaire at 3, 6, 12 months, 2, 5 and 10 years

Overall study start date
18/07/2018

Completion date
31/03/2032

Eligibility

Key inclusion criteria
1. Osteoarthritis of the knee with pain, disability and changes on standard of care clinical images (x-rays or MRI according to normal clinical practice) that, in the opinion of the treating clinician, warrants total knee replacement (TKR)
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
332

Total final enrolment
339

Key exclusion criteria
1. Osteoarthritis secondary to inflammatory arthropathy or intra-articular fracture as determined by the treating clinician
2. Revision surgery or need for complex implants, or any other implant than a standard Triathlon total knee replacement (TKR), 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 TKR, or surgery is otherwise contraindicated (for example, concurrent infection)

5. Previous randomisation in the present trial (i.e. other knee)
6. Unable to take part in 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
30/11/2020

Date of final enrolment
05/02/2024

Locations

Countries of recruitment
England

Scotland

United Kingdom

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

Study participating centre
Royal Infirmary of Edinburgh
51 Little France Crescent
Edinburgh
United Kingdom
EH16 4SA

Study participating centre
Glasgow Royal Infirmary
84, Castle Street
Glasgow
United Kingdom
G4 0SF

Study participating centre

The Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Royal National Orthopaedic Hospital
Brockley Hill
Stanmore
United Kingdom
HA7 4LP

Study participating centre
Royal Devon and Exeter NHS Foundation Trust
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
Portsmouth Hospitals NHS Trust
Southwick Hill Road
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
University Hospitals Coventry and Warwickshire
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Sponsor information

Organisation
University Hospitals Coventry and Warwickshire NHS Trust

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+44 (0)2476966196
R&DSponsorship@uhcw.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.uhcw.nhs.uk/

ROR
https://ror.org/025n38288

Organisation
University of Warwick

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+44 (0)2476523523
Sponsorship@warwick.ac.uk

Sponsor type
University/education

Website
https://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 Trial Steering Committee 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 success of the trial depends on the collaboration of doctors, nurses and researchers from across the UK. Equal credit will be given to those who have wholeheartedly collaborated in the trial, authorship will follow ICJME guidelines (http://www.icmje.org/recommendations/) and will require sustained or substantial involvement in the trial management and/or conduct. The final decision on authorship will rest with the CI and Co-CI, who will be first and last-author, correspondingly, on the final paper.
The trial will be reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines (www.consort-statement.org).

The intention to publish date will be approximately 1 year after the end of 12-month data follow-up - 31/07/2024. The researchers will also publish long-term results approximately one year after 10-year follow-up - 31/03/2033.

Intention to publish date
31/07/2025

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 06/01/2023:
The datasets generated during and/or analysed during the current study are/will be available upon request from Warwick Clinical Trials Unit (WCTU) Data Sharing Committee (WCTUDataAccess@warwick.ac.uk). De-identified data that underlie the results reported in the study will be available for non-commercial use, up to one year after the publication of the trial data, 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 with the sponsors, have an ethically approved protocol in place for use of the data, and agree to the approved protocol with the WCTU data-sharing committee. Data may be used for commercial purposes, according to the conditions above, but will need specific agreements in place prior to access being agreed upon, this may include a license fee. Analyses may include individual patient data meta-analyses or other purposes as agreed with the WCTU data sharing committee. Available data will include (but is not exclusive to) de-identified individual participant data that underlies the results reported in trial publications, the study protocol, statistical analysis plan, the master copy of the informed consent sheets and analytic codes used.

Previous IPD sharing statement:
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 4.0	26/11/2021	03/05/2023	No	Yes
Protocol article		09/06/2023	12/06/2023	Yes	No
HRA research summary			26/07/2023	No	No