Total vs Robotic bi-UniCompartmental Knee (TRUCK)Trial

Submission date 01/05/2014	Recruitment status No longer recruiting			
Registration date 17/06/2014	Overall study status Ongoing			
Last Edited 14/11/2023	Condition category Musculoskeletal Diseases			

[X] Prospectively registered

[] Protocol

[] Statistical analysis plan

[X] Results

[] Individual participant data

Plain English summary of protocol

Background and study aims

Osteoarthritis of the knee is a common condition that affects ~25% of the population over the age of 50. It occurs when there is damage to the knee joints that the body isn't able to repair. The exact cause is not known, but there are a number of factors thought to increase the risk of developing the condition. Symptoms include pain while walking (particularly when climbing the stairs or walking uphill), knees 'giving way' or difficulties in straightening the legs. The most common treatment option for osteoarthritis of the knee is a knee replacement. There are currently two main forms of knee replacement used, total knee replacement and unicompartmental knee replacement (used when only one side of the knee joint is damaged). Total knee replacement involves replacing both sides of the knee joint with metal implants separated by a plastic spacer or bearing. Unicompartmental knee replacement involves replacing only the side of the knee joint that is damaged, with smaller metal implants used to replace that side. Total knee replacement successfully provides pain relief in around 80% of cases, but the knee joint never feels 'normal' and patients often find that they can't do more physically demanding activities. Several studies have shown that 10-20% of patients are dissatisfied with the results of their total knee replacement surgery. In comparison, patients who undergo unicompartmental knee replacement surgery tend to have more normal walking patterns and a more normal-feeling knee with better function than if they had had a total knee replacement. However, it is estimated that only 25% of patients have osteoarthritis on only one side of the knee and are therefore eligible for the surgery and, as it's a complex procedure, many surgeons do not offer it as an option. Recently robotic assistive technology has been introduced to help surgeons perform unicompartmental knee replacement. The team at Glasgow Royal Infirmary have used this technology and found that implants are placed more accurately using it and that patients recover from surgery faster and, at least initially, have better outcomes. A natural extension of the unicompartmental knee replacement technique would be to use two unicompartmental knee replacements implanted at the same time on either side of the same knee joint this is called bi-unicompartmental knee replacement. This technique would allow surgeons to leave knee ligaments intact and replace only the damaged parts of the joint rather than removing the whole knee joint as occurs with total knee replacement. We believe that this surgical option would allow patients to walk more normally (a normal gait) and give them a significantly more normal feeling and acting knee than with a conventional total knee replacement. The purpose of the study is to determine if robotically assisted biunicompartmental knee replacement allows patients to walk with a more normal gait than is achieved with a traditional total knee replacement.

Who can participate?

Patients that have osteoarthritis on both sides of the knee but have intact knee ligaments.

What does the study involve?

Patents are randomly placed into one of two groups. Those in group one undergo standard total knee replacement surgery while those in group two undergo robotically assisted biunicompartmental knee replacement. The progress of each patient will then be followed up after 3 months, and then after 1, 2, 5 and, finally, 10 years, after surgery.

What are the possible benefits and risks of participating?

Robotic-assisted bi-unicompartmental knee replacement is a new technique and only around 20 cases have been undertaken using this technology worldwide. We therefore cannot tell how well this surgery will perform in the long term. The most significant risks for patients undergoing knee replacement surgery are infection within the new joint and in the longer term wearing out of the implant. We do not think that the risk of infection will be any higher for patients who receive robotic-assisted bi-unicompartmental knee replacement. We cannot predict how long robotic bi-unicompartmental knee replacement knee implants will last as the technique is too new. In addition, patients who take part in this study will have at least one CT scan of their knee (some patients will have two CT scans). This will involve additional exposure to X-rays.

Where is the study run from? Glasgow Royal Infirmary, Scotland, UK

When is the study starting and how long is it expected to run for? August 2014 to August 2027

Who is funding the study? Medical Research Council (UK)

Who is the main contact? Dr Iain Anthony iain.anthony@ggc.scot.nhs.uk Dr James Doonan (added 04/10/2019)

Study website https://w3.abdn.ac.uk/hsru/truck/

Contact information

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers Version 4.2 03/03/2021

Study information

Scientific Title

Explanatory comparative study of conventional total knee arthroplasty versus robotic assisted biunicompartmental knee arthroplasty

Acronym TRUCK

Study objectives

We hypothesise that robotic assisted Bi-UCKA surgery undertaken in appropriately selected patients can offer improved knee kinematics and proprioception in comparison to that afforded by TKA. Furthermore we hypothesise that accurate positioning of implants by robotic assistive technology will improve implant survivorship in Bi-UCKA to the levels achieved with TKA and UKA.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 01/08/2014, West of Scotland REC 4 (Dykebar Hospital Ward 11, Grahamston Road, Glasgow, PA2 7DE, United Kingdom; +44 (0)141 314 0213; wosrec4@ggc.scot.nhs.uk), ref: 14/WS /0134

Study design Randomized controlled trial

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

Osteoarthritis of the knee

Interventions

Patients will be randomised to receive either a standard total knee replacement or a robotically assisted bi-unicompartmental knee replacement. Randomisation will be via an online web interface and we will stratify by surgeon. Follow- will occur over a 10 year period at the following intervals (3 months, 1,2,5 and 10 years).

Intervention Type Other

Phase Not Applicable

Primary outcome measure

Percentage of patients with a bi-phasic (normal) moment curve during gait (level walking) measured at 1 year

Secondary outcome measures

1. Biomechanical performance: Gait during stair climb/descent and lunge, functional activity assessment (using electrogoniometers) at 1 year

2. Activity: Overall daily activity levels, maximum sport/physical activity, functional activity test times (stair climb, timed up and go) 1,2,5 and 10 years

3. Impairment: Range of motion, proprioception, quadriceps strength (short term outcome) and progression of OA in contralateral knee (long term outcome) at 1,2,5 and 10 years

 Clinical Outcomes: Clinical knee scores (Oxford Knee Score and American Knee Society Score), pain, analgesic use, complications, implant fixation and satisfaction at 1,2,5 and 10 years
Safety profile: Determined by revision rate, adverse events, robotic system errors and accuracy of implantation at 1,2,5 and 10 years

6. Accuracy of surgical implantation, determined by post-op CT analysis, at 1 year

Overall study start date

01/08/2014

Completion date

01/08/2028

Eligibility

Key inclusion criteria

1. Patients with medial and lateral compartment osteoarthritis of the knee with intact cruciate ligaments

2. Patients willing and able to give informed consent

Participant type(s)

Patient

Age group

Adult

Sex Both

Target number of participants 94

Total final enrolment 80

Key exclusion criteria

- 1. Patients with osteoarthritis limited to one compartment of the knee
- 2. Patients with rheumatoid arthritis
- 3. Patients with medial or lateral subluxation of the tibia on the femur
- 4. Patients with a varus or valgus deformity greater than 15°

- 5. Patients with a flexion contracture greater than 10°
- 6. Patients with rupture of either the ACL or PCL
- 7. Active or recent local infection
- 8. Patello-femoral OA greater than Kellgren and Lawrence grade III

9. Patients who have had previous surgery to the knee which may impact on the outcome of TKA or bi-unicompartmental knee arthroplasty

- 10. Patients with significant disease in other joints which might impact on their gait
- 11. Patients unable to give informed consent

Date of first enrolment

01/09/2014

Date of final enrolment 01/08/2018

Locations

Countries of recruitment Scotland

United Kingdom

Study participating centre Orthopaedic Research Unit 84 Castle Street Glasgow United Kingdom G4 0SF

Sponsor information

Organisation NHS Greater Glasgow and Clyde (UK)

Sponsor details NHS GGC R&D Office Western Infirmary Dumbarton Road Glasgow Scotland United Kingdom G11 6NT

Sponsor type Hospital/treatment centre

ROR https://ror.org/05kdz4d87

Funder(s)

Funder type Research council

Funder Name

Medical Research Council (MRC) (UK) MRC EME (12/12/12)

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/08/2029

Individual participant data (IPD) sharing plan

The data generated during this study are held in the Centre for Healthcare Randomised Trials (CTU) in Aberdeen. The data generated in this study will not be made generally publicly available due to ethical restrictions. However, the CI (Mr Mark Blyth, mark.blyth@ggc.scot.nhs.uk) is willing to partner and collaborate with research institutes and individual academics to provide anonymised data upon completion of a data-sharing agreement and updated ethics.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>	results	31/10/2020	13/08/2021	Yes	No
HRA research summary			26/07/2023	No	No
<u>Results article</u>		01/10/2021	06/11/2023	Yes	No
Results article		01/04/2022	06/11/2023	Yes	No