ISRCTN12151461 https://doi.org/10.1186/ISRCTN12151461

Total vs Robotic bi-UniCompartmental Knee (TRUCK)Trial

Submission date	Recruitment status	[X] Prospectively registered
01/05/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/06/2014	Ongoing	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/11/2023	Musculoskeletal Diseases	

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 bi-

unicompartmental 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 bi-unicompartmental 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
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Dr James Doonan (added 04/10/2019)

Contact information

Type(s)
Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Version 4.2 03/03/2021

Study information

Scientific Title
Explanatory comparative study of conventional total knee arthroplasty versus robotic assisted bi-unicompartmental 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

Study type(s)
Treatment

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

Key secondary outcome(s))
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
4. 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
5. 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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

Scotland

Study participating centre
Orthopaedic Research Unit
84 Castle Street
Glasgow
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Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

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

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?
Results article	results	31/10/2020	13/08/2021	Yes	No
Results article		01/10/2021	06/11/2023	Yes	No
Results article		01/04/2022	06/11/2023	Yes	No

HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes