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A comparison of knee replacement surgery and knee joint distraction for treating osteoarthritis of the knee

Submission date
13/01/2020

Recruitment status
No longer recruiting

Registration date
16/01/2020

Overall study status
Completed

Last Edited
04/10/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Knee replacement surgery (arthroplasty) is a common operation that involves replacing a damaged, worn or diseased knee with an artificial joint. This study will investigate a new procedure to treat the symptoms of knee osteoarthritis known as knee joint distraction (KJD). The knee joint is where the thigh bone (femur) and shin bone (tibia) meet. The ends of each bone are covered in a layer of cartilage, which acts like a shock absorber in the joint. In osteoarthritis, the cartilage becomes rough and thin and the ends of the bones become exposed.

In the KJD procedure, a metal frame is fixed around the knee while the patient is under general anaesthetic or a spinal block. The frame is attached to pins that are drilled through the tibia and the femur. The joint is pulled slightly apart using the frame, which usually stays in place for 2 to 3 months. During this time, the person is able to walk. This is to take the weight off the joint and encourage the cartilage to repair itself.

Who can participate?
People under 65 years of age who need a knee replacement

What does the study involve?
Participants will be randomly assigned to have either KR (standard) or KJD (intervention).
The standard group will have a knee replacement in line with their hospital's usual standard of care. The intervention arm will have an external frame attached to their leg for 6 weeks which pulls the knee joint apart about 5mm, allowing the cartilage in the joint to repair. They will then return to hospital for the frame to be removed. Both groups will attend study visits at 3, 12 and 24 months after their surgery where they will fill in five short questionnaires and have their knee function assessed. The intervention group will also have an x-ray at these visits to assess the amount of cartilage healing in their knee joint. Participants will also be sent short questionnaires to fill in at home at 6 months after surgery.
Interviews will also be carried out with a small number of participants to evaluate the process.

What are the possible benefits and risks of participating?
The benefits are the same as having this surgery outside of the study. However, the information from the study will help us to learn more about the most effective operation for knee osteoarthritis and will help improve treatment in the future. There are no specific risks of taking part in the study other than the risks of having surgery. The risks of the two operations are thought to be similar.

Where is the study run from?
The study is being run by Leeds Clinical Trials Research Unit and the lead hospital site is Leeds Teaching Hospitals Trust.

When is the study starting and how long is it expected to run for?
January 2020 to March 2022

Who is funding the study?
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC), UK

Who is the main contact?
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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
270040

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 43723, IRAS 270040

Study information

Scientific Title
Knee ARthroplasty versus joint Distraction Study for osteoarthritis (KARDS)

Acronym
KARDS

Study objectives
Knee Joint Distraction is non inferior to Knee Replacement in the treatment of knee osteoarthritis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/01/2020, Yorkshire & The Humber - Leeds East REC (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ; +44 (0)207 1048 088; nrescommittee.yorkandhumber-leedseast@nhs.net), ref: 19/YH/0368

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Osteoarthritis

Interventions

This is a pragmatic, non-blinded, multi-centre randomised controlled trial designed to establish the clinical and cost-effectiveness of KJD in an NHS setting. 344 participants will be recruited from secondary care orthopaedic outpatient clinics following referral by their GP for symptoms of knee osteoarthritis. Potential participants will be identified by the local trial team and approached in clinic by their treating surgeon and given a participant information sheet. They will be given as long as possible to consider the trial before consenting to take part, ideally a minimum of 24 hours but this will not be imposed if a participant wants to consent sooner, is fully informed and has had sufficient time to consider the trial. Those who choose not to consent will have their non-identifiable information, including age, gender and reason for non-consent, added to the non-registration log.

Participants who wish to take part will attend a trial visit up to 6 weeks before their planned date of surgery. At this visit informed consent will be taken by the PI or delegated member of the trial team and the participant will complete a questionnaire pack and have their knee function assessed for research purposes. This will be done with a timed up and go test (which involves standing from a sitting position, walking three metres and then returning to a sitting position) and range of motion assessment (involved the leg being extended as far as possible and the angle measured, and then flexing the leg as far as possible and having the angle measured again). They will be randomised to an arm of the trial and will be informed of their treatment. They will also have an x-ray of their knee with the leg bent, which will be used in both groups to assess the severity of their osteoarthritis and in the intervention group will also provide a baseline measurement to assess cartilage healing.

On the day of surgery the participant will be prepared for surgery in line with local standard care, the treating team will ensure they are still eligible for the trial and the participant will complete one questionnaire. They will then have surgery according to their randomised allocation. Details of the operation will be recorded by the trial team.

The KR arm will be assessed post-operatively in line with local standard care and they will be discharged when fit. Before discharge they will have x-rays of their treated knee which are usually performed as part of standard care but will also be used by the trial team to confirm the details of the surgery. The KJD arm will remain in hospital (or return daily) for up to 7 days to complete the distraction process. They will then have an x-ray of their treated knee to confirm the distraction achieved, will be given advice about pinsite care in line with local practice and will then be discharged with the frame in place. They will return to hospital 6 weeks later to have another x-ray to check the final distraction, after which the frame will be removed under anaesthesia and they will be able to return home the same day.

All participants will attend study visits at 3, 12 and 24 months post-surgery where their knee function will be assessed, complications will be monitored and they will complete a questionnaire pack. The KJD arm will also have an x-ray at these visits to assess cartilage healing. At 6 months post-surgery participants will be sent questionnaire pack to complete by post and /or online. They will be sent email or text reminders if they consented to this on the consent form.

Qualitative interviews will be conducted with a sample of participants, people who decline to participate and members of staff involved in the trial at sites (e.g. surgeons, research nurses). These interviews will be conducted by telephone or face to face and will be arranged at a time convenient to the participant. Interviews will be audio recorded with consent. During the pilot phase (first 12 months of recruitment) patient interviews will take place shortly after discharge from hospital, and some participants may be re-interviewed around three months later. During

the main trial participant interviews will take place around three months after treatment. Staff interviews will take place during the pilot phase; each member of staff will be interviewed up to twice, once during the set up or shortly after opening, and once after recruitment has started.

Participants will also be asked for consent for longer-term outcomes to be followed up after the KARDS trial using routinely collected data from the National Joint Registry. This consent is optional and does not affect their participation in the KARDS trial.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Knee Injury & Osteoarthritis Outcomes Score (KOOS) pain component measured at 12 months following surgery

Key secondary outcome(s))
1. Patient reported outcomes and Quality of life outcomes (KOOS, Pain VAS, Oxford Knee Score) at baseline and 3, 6, 12, and 24 months after surgery
2. Objective assessment of knee function (Active range of movement and a timed up and go test) at baseline and 3, 12, and 24 months post-surgery
3. Incidence of complications (intra-operative, post-operative and any unplanned surgical interventions on the affected knee) at 3, 12, and 24 months post-surgery
4. Joint space width (assessed quantitatively from standardised radiographs) at 3, 12, and 24 months post-surgery
5. Cost-effectiveness (EQ-5D-3L and Health Resource Utilisation and Private Costs Questionnaire) at 3, 6, 12, and 24 months post-surgery
6. Implementation processes and intervention fidelity (assessed quantitatively using a surgical CRF and assessments of radiographs, and assessed qualitatively) in the first 12 months of recruitment
7. Qualitative evaluation of participant experiences measured using interviews after discharge from hospital and 3 months later

Completion date
30/11/2023

Eligibility

Key inclusion criteria
1. Age > = 18 years and < = 65 years at the time of signing the Informed Consent form
2. Symptoms (pain and/or reduced function) severe enough to warrant knee replacement, in the opinion of the treating clinician
3. Pre-operative leg alignment not requiring correction, in the opinion of the treating clinician
4. Intact collateral knee ligaments, in the opinion of the treating clinician
5. Fixed flexion deformity < = 10 degrees of the involved knee

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Bone density not sufficient to support pins for 6 weeks, in the opinion of treating clinician
2. Isolated patello-femoral OA, in the opinion of the treating clinician
3. Complete joint space obliteration in both medial and lateral tibio-femoral compartments as seen on weight bearing AP knee radiograph
4. A known diagnosis of inflammatory arthritis
5. Presence of a previous joint replacement in any limb
6. Surgical treatment of involved knee within the past 6 months (excluding arthroscopy)
7. Previous knee joint distraction on the involved knee
8. Previously participated in the KARDS trial
9. Weight > 120kg
10. Pregnant or lactating (confirmed by participant)
11. Active cancer (currently diagnosed and under treatment)
12. Unable to complete all trial procedures (e.g. attend follow up visits, complete questionnaires)
13. Unable to provide informed consent (cognitive disorder such as dementia, psychiatric illness)

Date of first enrolment
31/03/2021

Date of final enrolment
17/10/2022

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
St James University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Hull Royal Infirmary
Hull and East Yorkshire Hospitals NHS Trust
Anlaby Road
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HU3 2JZ

Study participating centre
John Radcliffe Hospital
Headley Way
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OX3 9DU

Study participating centre
Walsgrave General Hospital
Clifford Bridge Road
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United Kingdom
CV2 2DX

Study participating centre
NHS Lothian
2 - 4 Waterloo Place
Edinburgh
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EH1 3EG

Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 17/122/06

Funder Name
National Institute for Health Research (NIHR) (UK)

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?
Results article		11/07/2024	12/07/2024	Yes	No
Protocol article	Protocol	30/06/2022	01/07/2022	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet version 1.0	11/11/2025	11/11/2025	No	Yes
Plain English results		04/10/2024	04/10/2024	No	Yes