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Should we replace the back of the knee cap all of the time or some of the time in patients having knee replacement surgery? A trial comparing patient outcomes and the cost to the NHS.

Submission date
13/02/2023

Recruitment status
Recruiting

Registration date
27/02/2023

Overall study status
Ongoing

Last Edited
05/11/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Improving pain and mobility after total knee replacement (TKR) surgery has been highlighted as a research priority by patients. TKR surgery is common. 109,000 are carried out every year in the UK. It is performed to help patients with pain from disabling arthritis.

TKR involves replacing the bottom of the thighbone (femur) and the top of the leg bone (tibia) with artificial implants. Surgeons also decide on one of two options for treating the kneecap:

1) The kneecap (patella) is not changed.

2) The surgeon attaches a separate artificial implant to the back of the kneecap, which may reduce further wear or pain. This is known as resurfacing the kneecap.

National guidance is that always resurfacing is better than never resurfacing.

Many surgeons make an individual choice about whether to resurface the kneecap. This is based on factors such as pain and the condition of the kneecap. We call this selective resurfacing.

Our study will compare patients undergoing TKR who all have the kneecap resurfaced with those who have it selectively resurfaced.

Who can participate?

Over 4 years we will recruit 530 patients having TKR at 15 or more NHS England hospitals.

What does the study involve?

Participants will be randomly split into two equal groups of 265. All patients in one group will have their kneecap resurfaced. In the other, the surgeon will decide during the operation whether or not to resurface the kneecap.

All other aspects of care will be the same. Follow-up questionnaires at 3-, 6- and 12 months after surgery will be completed. The questionnaires collect data on quality of life, symptoms and pain in the knee, complications of surgery, need for further surgery, and costs to the NHS and patients.

This will find out which strategy gives better outcomes for patients, and whether one is better value for money for the NHS.

What are the possible benefits and risks of participating?
The surgical intervention of interest in this study is replacing the knee cap (also known as patellar resurfacing) some of the time, compared with the current standard of care recommended by national authorities (NICE) which is performing patellar resurfacing all of the time. NICE guidance states that patellar resurfacing is not associated with safety concerns. Therefore patellar resurfacing during knee replacement is a commonly used procedure which poses no additional risks to routine care.

Study procedures will include questionnaires at each listed time point. All other study assessments will require participant's time, however no other inconvenience or risk is expected above that of routine care and follow-up.

There is unlikely to be any direct benefit as a result of participation in the study. Investigation of whether to utilise patellar resurfacing in patients with knee arthritis all of the time or some of the time will help to inform future treatment of patients undergoing primary total knee replacement surgery and could result in reduced costs for the NHS. The main benefit of this study is the provision of high-quality evidence to address this important area of clinical uncertainty that has been highlighted by NICE in their recent evidence publication.

Where is the study run from?
North Bristol NHS Trust (UK)

When is the study starting and how long is it expected to run for?
April 2022 to March 2026

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

Who is the main contact?
PART-trial@bristol.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
320677

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 54796, NIHR131850

Study information

Scientific Title
The clinical and cost-effectiveness of elective primary total knee replacement with PAtellar Resurfacing compared to selective patellar resurfacing. A pragmatic multicentre randomised controlled Trial with blinding (PART)

Acronym
PART

Study objectives
Following primary total knee replacement, there will be no difference in the mean Oxford Knee Score at 1 year postoperatively in patients who have undergone patellar resurfacing compared with those who have undergone selective patellar resurfacing.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 16/01/2023, Wales REC 2 (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 (0) 7920 565664; Wales.REC2@wales.nhs.uk), ref: 22/WA/0367

Study design
Interventional multicentre pragmatic parallel two-group superiority randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Total knee replacement with patellar resurfacing compared to selective patellar resurfacing

Interventions
Randomisation:
Randomisation will be carried out intraoperatively once total knee replacement has been performed and the size of the patella can be measured. Participants will be allocated in a 1:1 ratio to either always patella resurfacing or selective patella resurfacing.

Intervention/Health technologies being assessed:
Experimental: Selective resurfacing of the patella based on pre-operative factors such as pain and function and intraoperative assessment of the patella by surgeons.
Control: Always resurfacing of the aptella

Follow up:
Participants who agree to participate in the study will be followed up at approximately 3, 6, and 12 months postrandomisation for information on knee function, activity, HRQoL (Health Related Quality of Life), return to work and resource use. If further funding is awarded, patients will be followed up for a total of ten years. Patients may be contacted via phonecall, text message or email. In the event that unforeseen circumstances prevent sites from being able to carry out their normal activities, they should contact the Bristol Trials Centre (BTC) who will do everything

they can to help. This may include, but is not limited to, sending out questionnaires and reminders on their behalf.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Oxford Knee Score (OKS) questionnaire 1 year after randomisation

Key secondary outcome(s))
Patient reported questionnaires at 3 months, 6 months and 1 year post randomisation:
1. Oxford Knee Score
2. Knee Injury & Osteoarthritis Outcome Score
3. EQ-5D-5L Quality of health questionnaire

Resource data will be collected at 3 months, 6 months and 1 year post randomisation, specifically:
4. Postoperative complications
5. Need for further surgery
6. Further patella resurfacing surgery
7. Resource use and costs within 1 year
8. Mortality data

Completion date
31/03/2026

Eligibility

Key inclusion criteria
1. 18 years of age or older
2. Elective primary Total Knee Replacement (TKR) for primary Osteoarthritis (OA)
3. Resident of England (English postcode) and surgery in an NHS England hospital

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria

1. Revision TKR
2. Unicompartmental knee replacement
3. Primary TKR with:
3.1. need for constrained implants (e.g., constrained condylar or hinge),
3.2. isolated patellofemoral OA,
3.3. history of septic arthritis,
3.4. diagnosis other than primary OA
4. Intra-operative patellar thickness insufficient for safe patellar resurfacing as determined by the treating surgeon (patellar thickness will be recorded in the case report forms for monitoring purposes)
5. Patient unable/unwilling to adhere to trial procedures
6. Patient unable to provide written informed consent.
7. Participating in another study that may affect the outcomes of this trial or that does not permit co-enrolment in another study or where co-enrolment would be burdensome to the patient. This will be assessed on a case-by-case basis by the local PI, in consultation with the co-CIs.

Date of first enrolment
17/04/2023

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bedfordshire Hospitals NHS Foundation Trust
Lewsey Road
Luton
United Kingdom
LU4 0DZ

Study participating centre
Milton Keynes University Hospital NHS Foundation Trust
Standing Way
Eaglestone
Milton Keynes
United Kingdom
MK6 5LD

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
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United Kingdom
S5 7AU

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Musgrove Park Hospital (taunton)
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
Royal Cornwall Hospital (treliske)
Treliske
Truro
United Kingdom
TR1 3LJ

Study participating centre

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Clifford Bridge Road
Coventry
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CV2 2DX

Study participating centre
Darent Valley Hospital
Darenth Wood Road
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DA2 8DA

Study participating centre
Salisbury District Hospital
Odstock Road
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SP2 8BJ

Study participating centre
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YO31 8HE

Study participating centre
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SE13 6LH

Sponsor information

Organisation
North Bristol NHS Trust

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

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		03/06/2024	04/06/2024	Yes	No
HRA research summary			26/07/2023	No	No
Participant information sheet	version 2.0	08/02/2023	24/02/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2.0	08/02/2023	24/02/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes