ISRCTN03013488 https://doi.org/10.1186/ISRCTN03013488

Total or partial knee arthroplasty trial

Submission date
08/04/2009

Recruitment status
No longer recruiting

Registration date
09/04/2009

Overall study status
Completed

Last Edited
10/12/2025

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
Osteoarthritis is a condition that causes the joints to become painful and stiff. Osteoarthritis of the knee affects a large proportion of the population and this is set to increase over time. Quite often the arthritis is limited to one area of the joint, particularly the inside of the joint. Patients can either have a partial knee replacement or a total knee replacement. The partial knee replacement, as its name suggests, involves the removal and replacement of only the diseased part of the joint. Total knee replacement involves the removal and replacement of the entire knee joint. Total knee replacement is easier to do and considered more reliable (lower failure /revision rate), but it involves cutting away healthy parts of the joint. Partial knee replacement retains healthy tissue and usually achieves better functional results, but is more difficult to do and can have an increased failure/revision rate. There are also significant cost advantages for the healthcare system for partial knee replacements. Unfortunately we currently do not know which type of replacement is best for these particular patients. Hence, the aim of this study is to directly compare the clinical and cost-effectiveness of total knee replacements versus partial knee replacements for patients with osteoarthritis.

Who can participate?
Patients aged 40 or over with osteoarthritis

What does the study involve?
The study is carried out at the local hospital where the patient would normally have their knee replacement. Patients recruited to the study are randomly allocated to undergo either total or partial knee replacement surgery. Patients are then followed up for 10 years after the surgery. The measurements taken to assess which type of knee replacement is better are predominantly patient based. This means that the measurements directly assess how the patient, rather than the surgeon, feels about the outcome after their operation.

What are the possible benefits and risks of participating?
Not provided at time of registration

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

When is the study starting and how long is it expected to run for?
November 2009 to December 2018

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Prof. David Beard
david.beard@ndorms.ox.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof David Beard

ORCID ID
https://orcid.org/0000-0001-7884-6389

Contact details
Nuffield Department of Orthopaedic, Rheumatology & Musculoskeletal Sciences
Windmill Road
Headington
Oxford
United Kingdom
OX3 7LD
+44 (0)1865 227695
david.beard@ndorms.ox.ac.uk

Type(s)
Scientific

Contact name
Ms Loretta Davies

Contact details
Surgical Intervention Trials Unit
NDORMS
Botnar Research Centre
University of Oxford
Nuffield Orthopaedic Centre
Windmill Road
Oxford
United Kingdom
OX3 7LD
+44 (0)1865 737210
loretta.davies@ndorms.ox.ac.uk

Additional identifiers

ClinicalTrials.gov (NCT)
NCT01352247

Protocol serial number
HTA 08/14/08; Version 1

Study information

Scientific Title
Clinical and cost-effectiveness of total knee replacements versus partial knee replacements for patients with medial compartment osteoarthritis: a multicentre randomised controlled trial

Acronym
TOPKAT

Study objectives
To assess the clinical and cost-effectiveness of total knee replacements versus partial knee replacements for patients with medial compartment osteoarthritis.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/081408

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxfordshire REC C, 04/09/2009, ref: 09/H606/88

Study design
Multicentre prospective superiority randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Osteoarthritis/avascular necrosis

Interventions
Total knee replacement surgery versus unicompartmental knee replacement surgery. Patients will be followed up for 10 years post surgery. Going on the average waiting list times of 3 months, the approximate involvement in the study for each participant (recruitment, treatment and follow up) would be 10 years and 3 months.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Oxford Knee Score: a patient based validated and effective measure of change over time questionnaire. Both the absolute and the change scores will be analysed at 5- and 10-year points post-operation.

Key secondary outcome(s))
1. American Knee Society Score: to measure the range of motion and function of the knee, measured at 2 months, 1, 5 and 10 years post-surgery
2. UCLA Activity Score: to measure how active the patient is, measured at 2 months, 1, 5 and 10 years post-surgery
3. X-ray to check for immediate problems, assess the outcome of surgery, complications and make long-term predictions, measured at 2 months, 1, 5 and 10 years post-surgery
4. EQ-5D: to provide data for the economic evaluation, measured at 2 months, 1, 2, 3, 4, 5, 7 and 10 years post-surgery
5. Lund Score: to measure patient satisfaction, measured at 2 months, 1, 2, 3, 4, 5, 7 and 10 years post-surgery
6. Other outcomes, e.g., kinematic and gait assessments, measured at 2 months, 1, 5 and 10 years post-surgery

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Medial osteoarthritis with exposed bone on both femur and tibia or avascular necrosis
2. Functionally intact anterior cruciate ligament (superficial damage or splitting is acceptable)
3. Full thickness lateral cartilage
4. Correctable intra-articular varus deformity (suggestive of functionally intact medical cruciate ligament)
5. Medically fit showing an American Society of Anaesthesiologists (ASA) grade 1 or 2
6. Expectancy of over 10 years of active life
7. Aged 40 years or over, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
528

Key exclusion criteria

1. Require revision knee replacement surgery
2. Have rheumatoid arthritis or other inflammatory disorders
3. Are likely to benefit from a specific prosthesis type
4. Are unlikely to be able to perform required clinical assessment tasks
5. Have symptomatic foot, hip or spinal pathology

Date of first enrolment
01/01/2010

Date of final enrolment
30/09/2013

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
Nuffield Department of Orthopaedic, Rheumatology & Musculoskeletal Sciences
-
Oxford
England
OX3 7LD

Study participating centre
Royal Gwent Hospital
Aneurin Bevan University Health Board
Cardiff Road
Newport
Wales
NP20 2UB

Study participating centre
Musgrave Park Hospital
Belfast Health and Social Care Trust
Stockman's Lane
Belfast

Northern Ireland
BT9 7JB

Study participating centre
Chesterfield Royal Hospital
Chesterfield Royal Hospital NHS Foundation Trust
Calow
Chesterfield
England
S44 5BL

Study participating centre
University Hospital of North Durham
County Durham and Darlington NHS Foundation Trust
North Road
Durham
England
DH1 5TW

Study participating centre
Royal Blackburn Teaching Hospital
East Lancashire Hospitals NHS Trust
Haslingden Road
Blackburn
England
BB2 3HH

Study participating centre
Great Western Hospital
Great Western Hospitals NHS Foundation Trust
Marlborough Road
Swindon
England
SN3 6BB

Study participating centre
Harrogate District Hospital
Harrogate and District NHS Foundation Trust
Lancaster Park Rd

Harrogate
England
HG2 7SX

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

Study participating centre
Medway Maritime Hospital
Maidstone and Tunbridge Wells NHS Trust
Windmill Road
Gillingham
England
ME7 5NY

Study participating centre
Pinderfields Hospital
Mid Yorkshire Hospitals NHS Trust
Aberford Road
Wakefield
England
WF1 4DG

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

Study participating centre
Woodend Hospital
NHS Grampian
Eday Road

Aberdeen
Scotland
AB15 6XS

Study participating centre
Southmead Hospital Bristol
North Bristol NHS Trust
Southmead Road
Westbury-on-Trym
Bristol
England
BS10 5NB

Study participating centre
The Cumberland Infirmary
North Cumbria University Hospitals NHS Trust
Newtown Road
Carlisle
England
CA2 7HY

Study participating centre
University Hospital of North Tees
North Tees and Hartlepool NHS Foundation Trust
Hardwick
Stockton on Tees
England
TS19 8PE

Study participating centre
Royal United Hospitals Bath
NHS Foundation Trust
Combe Park
Bath
England
BA1 3NG

Study participating centre
King's Mill Hospital
Sherwood Forest Hospitals NHS Foundation Trust
Mansfield Road

Sutton-in-Ashfield
England
NG17 4JL

Study participating centre
Torbay Hospital
South Devon Healthcare NHS Foundation Trust
Lowes Bridge
Torquay
England
TQ2 7AA

Study participating centre
Stepping Hill Hospital
Stockport NHS Foundation Trust
Poplar Grove
Hazel Grove
Stockport
England
SK2 7JE

Study participating centre
Hillingdon Hospitals
The Hillingdon Hospitals NHS Trust
Pield Heath Road
Uxbridge
England
UB8 3NN

Study participating centre
Ipswich Hospital
Ipswich Hospital NHS Trust Heath Road
Ipswich
England
IP4 5PD

Study participating centre
Leicester General Hospital
University Hospitals of Leicester NHS Trust
Gwendolen House
Gwendolen Road

Leicester
England
LE5 4QF

Study participating centre
Royal Stoke University Hospital
University Hospitals of North Midlands NHS Trust
Newcastle Road
Stoke-on-Trent
England
ST4 6QG

Study participating centre
Southampton General Hospital
University Hospital Southampton NHS Foundation Trust
Tremona Road
Southampton
England
SO16 6YD

Study participating centre
Lincoln County Hospital
United Lincolnshire Hospitals NHS Trust
Greetwell Road
Lincoln
England
LN2 5QY

Study participating centre
Pilgrim Hospital Boston
United Lincolnshire Hospitals NHS Trust
Sibsey Road
Boston
England
PE21 9QS

Study participating centre
Yeovil District Hospital
Yeovil District Hospital NHS Foundation Trust
Higher Kingston
Yeovil

England
BA21 4AT

Sponsor information

Organisation
University of Oxford (UK)

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

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?
	early results				

Results article		01/10/2017	13/05/2019	Yes	No
Results article	5-year results	31/08/2019	22/07/2019	Yes	No
Results article	results	01/04/2020	06/05/2020	Yes	No
Protocol article	protocol	12/09/2013		Yes	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