

Total or partial knee arthroplasty trial

Submission date 08/04/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/04/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/12/2025	Condition category Musculoskeletal Diseases	<input type="checkbox"/> 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
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Contact information

Type(s)
Scientific

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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

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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
Study website	Study website	11/11/2025	11/11/2025	No	Yes