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Total or partial knee arthroplasty trial

Submission date	Recruitment status	[X] Prospectively registered
08/04/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/04/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/05/2020	Musculoskeletal Diseases	

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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Study website
https://viis.abdn.ac.uk/HSRU/topkat/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01352247

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/11/2009

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

Age group
Adult

Sex
Both

Target number of participants
500

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
England

Northern Ireland

Scotland

United Kingdom

Wales

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

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

Study participating centre
Musgrave Park Hospital
Belfast Health and Social Care Trust
Stockman's Lane
Belfast
United Kingdom
BT9 7JB

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

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

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

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

Study participating centre
Harrogate District Hospital
Harrogate and District NHS Foundation Trust
Lancaster Park Rd
Harrogate
United Kingdom
HG2 7SX

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

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

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

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

Study participating centre
Woodend Hospital
NHS Grampian
Eday Road
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United Kingdom
AB15 6XS

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

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

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

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

Study participating centre
King's Mill Hospital
Sherwood Forest Hospitals NHS Foundation Trust
Mansfield Road
Sutton-in-Ashfield
United Kingdom
NG17 4JL

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

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

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

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

Study participating centre
Leicester General Hospital
University Hospitals of Leicester NHS Trust
Gwendolen House
Gwendolen Road
Leicester
United Kingdom
LE5 4QF

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

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

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

Study participating centre

Pilgrim Hospital Boston
United Lincolnshire Hospitals NHS Trust
Sibsey Road
Boston
United Kingdom
PE21 9QS

Study participating centre
Yeovil District Hospital
Yeovil District Hospital NHS Foundation Trust
Higher Kingston
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BA21 4AT

Sponsor information

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University of Oxford (UK)

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Sponsor type
University/education

Website
http://www.admin.ox.ac.uk/rso/clinical

ROR
https://ror.org/052gg0110

Funder(s)

Funder type

Government

Funder Name
Health Technology Assessment Programme

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publications include a final report to the funding body, National Institute for Health Research (NIHR), as well as publications in high-impact peer reviewed journals. The main trial results paper is planned for 2019.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made 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	protocol	12/09/2013		Yes	No
Results article	early results	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