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A randomised controlled trial of different knee prostheses

Submission date	Recruitment status	[ ] Prospectively registered
25/04/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/04/2003	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/08/2023	Musculoskeletal Diseases	

Plain English summary of protocol

Background and study aims
In knee replacement surgery (knee arthroplasty), all or part of a damaged knee joint is replaced with metal and/or plastic components. Various approaches to knee replacement surgery are used and different designs are available. It was not clear which works better or is safer. The aim of this study is therefore to answer three questions. Should the back surface of the knee cap routinely be resurfaced with an additional plastic part? Should the metal and plastic parts of the knee replacement be firmly fixed together (fixed bearing), or should the plastic part be mobile to allow more normal knee movement (mobile bearing)? Should the part of the knee replacement that attaches to the shin bone (the tibial component), be all plastic or plastic with a metal backing?

Who can participate?
Patients undergoing knee replacement surgery

What does the study involve?
Participants can take part in one or two of the four study comparisons depending on the extent and type of disease in their knee. In each comparison participants are randomly allocated to one of two knee operations (i.e., knee cap resurfacing or no resurfacing; fixed bearing or mobile bearing; all plastic or plastic-and-metal tibial component; partial or total knee replacement). All participants are asked to complete postal questionnaires after three months and annually thereafter up to 20 years after the surgery. The postal questionnaires ask about knee function, general quality of life and healthcare costs. Information is also collected about any complications and further hospital admissions and operations.

What are the possible benefits and risks of participating?
Participants may not benefit personally from taking part in the study but they will be helping doctors to assess which operations are best and safest. We do not think there are any additional risks or disadvantages to participants. Whichever group they are allocated, their operation will be performed by an experienced orthopaedic surgeon. Steps are always taken to make sure that any possible risks are minimised. As part of routine care, participants will be well informed of potential risks.

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

When is the study starting and how long is it expected to run for?
December 1998 to June 2023

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

Who is the main contact?
Prof. David Murray, david.murray@ndorms.ox.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 95/10/01

Study information

Scientific Title
A randomised controlled trial of different knee prostheses

Acronym
KAT (Knee Arthroplasty Trial)

Study objectives
A UK wide network of clinical centres will be established to conduct randomised partial factorial trials on current practice of knee replacement. Independent management by health services research units is a feature of the application. Individual surgeons will be invited to consider areas of uncertainty concerning current knee prosthetic and participate in randomisation between certain design aspects of knee replacement systems which are otherwise similar in all other respects.
The project will require two phases, each of six years. At end of first phase, the trial will demonstrate short to medium-term variations in costs and outcome relating to the four management options. The second phase is necessary in order to demonstrate prosthesis design-related adverse events. This trial will produce authoritative data to inform purchasers, providers, consumers and clinicians about this very commonly performed procedure in the NHS.

More details can be found at:
1. http://www.nets.nihr.ac.uk/projects/hta/951001
2. http://w3.abdn.ac.uk/HSRU/CHART/public/trials/TrialDetails.aspx?page=current-trials&tid=15

Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0003/53724/PRO-95-10-01.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Multi-centre Research Ethics Committee for Scotland, 30/11/1998, ref: MREC/98/0/100

Study design
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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Primary knee replacement surgery

Interventions
Current interventions as of 23/01/2009:
The trial is evaluating four aspects of knee replacements:
1. Metal backing of the tibial component compared with a single high density polyethylene component (350 participants)
2. Patellar resurfacing compared with no resurfacing (1400 participants)
3. A polyethylene mobile bearing component between the tibia and femur compared with a fixed bearing arthroplasty (350 participants)
4. Uni-compartmental arthroplasty compared with total knee replacement (350 participants)

Individual patients can participate in a maximum of two comparisons and then only if the surgeon responsible for care is substantially uncertain about these particular aspects.

Previous interventions:
The four management options are:
1. Metal versus non-metal backing of the tibial component
2. Whether to resurface the patella
3. Unicompartmental versus total knee arthroplasty
4. Mobile versus fixed bearing

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measures as of 23/01/2009:
Oxford Knee Score (postal questionnaire) at 3 months and then annually thereafter.

Previous primary outcome measures:
Outcomes will be in terms of complications and patient-assessed pain and function, principally conducted by post.
Costings include those relating to
1. Early complications expected immediately post operatively from medical effects
2. Medium-term complications such as dislocation and infection
3. Late complications of wear, loosening and infection.

Secondary outcome measures
Added as of 23/01/2009:
Complications and patient-assessed pain and function, assessed principally by postal questionnaires including:
1. SF-12
2. EQ-5D
3. Questions about any further hospital admissions and surgery
4. Costings:
4.1. Early complications expected immediately post-operatively from medical effects
4.2. Medium-term complications such as dislocation and infection
4.3. Late complications of wear, loosening and infection

Questionnaires are completed at 3 months and then annually thereafter.

Overall study start date
31/12/1998

Completion date
30/06/2023

Eligibility

Key inclusion criteria
Added as of 23/01/2009:
1. A decision has been made to have primary knee replacement surgery
2. The surgeon has no clear preference for a specific option in at least one of the comparisons
3. Both males ane females, no age limits

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
2,450

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/07/1999

Date of final enrolment
31/12/2002

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
University of Oxford
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Study participating centre
University of Aberdeen
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Sponsor information

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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

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
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Baseline characteristics, and 2-year functional outcomes	01/01/2009		Yes	No
Results article	cost-effectiveness analysis results	30/01/2012		Yes	No
Results article	Clinical effectiveness and cost-effectiveness after a median of 10 years follow-up	01/03/2014		Yes	No