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Sub-vastus versus Medial parapatellar Arthrotomy for total Knee replacement

Submission date	Recruitment status	[_] Prospectively registered
21/11/2005	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/11/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/10/2022	Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0158124154

Study information

Scientific Title
Sub-vastus versus Medial parapatellar Arthrotomy for total Knee replacement

Acronym
SMAK

Study objectives
In patients undergoing primary or tri-compartmental knee replacement the sub-vastus approach is significantly superior to the standard medial parapatelar approach in terms of short and long term knee function.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval was obtained from the local ethics committee for the trial.

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

Health condition(s) or problem(s) studied
Total knee replacement

Interventions
Standard medial parapatellar approach or sub-vastus approach for primary bi- or tri-compartmental total knee replacement.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure

Knee Society Score at 52 weeks.

Secondary outcome measures
1. EuroQol-5D
2. Western Ontario and McMaster Universities (WOMAC) osteoarthritis index
3. 36-item short form health survey (SF-36)
4. Time to normal activities/return to function
5. Pain
6. Complications
7. Surgeon's ease of exposure
8. Length of hospital stay

Overall study start date
01/02/2001

Completion date
01/08/2004

Eligibility

Key inclusion criteria
1. They require a bi- or tri- compartmental knee replacement
2. They require a unilateral knee replacement
3. They have given their informed consent
4. The surgeon has no clear preference for either of the approaches

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
231

Key exclusion criteria
1. They need a revision knee replacement
2. They have had, or will require a major arthrotomy in the other knee in a 12 month period
3. They have had previous open surgery in or around the knee in the previous 12 months e.g. high tibial osteotomy, femoal osteotmy, open reduction internal fixation (ORIF) for fracture, patellar realignment, patellectomy and open menisectomy
4. They require a bi-lateral knee replacement at a single visit
5. They have a valgus angle of degrees or more

Date of first enrolment
01/02/2001

Date of final enrolment
01/08/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
HOSU Locomotor Directorate
Stoke-on-Trent
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Sponsor information

Organisation
University Hospital of North Staffordshire NHS Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.uhns.nhs.uk/

Funder(s)

Funder type
Government

Funder Name
NHS R&D Support Funding (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		31/07/2006		Yes	No
Results article		31/07/2006		Yes	No