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Sub-vastus versus Medial parapatellar Arthrotomy for total Knee replacement

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
Knee Society Score at 52 weeks.

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
HOSU Locomotor Directorate
Stoke-on-Trent
United Kingdom
ST4 6QG

Sponsor information

Organisation
University Hospital of North Staffordshire NHS Trust (UK)

Funder(s)

Funder type
Government

Funder Name
NHS R&D Support Funding (UK)

Results and Publications

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?
Results article		31/07/2006		Yes	No
Protocol article		31/07/2006		Yes	No