

Sub-vastus versus Medial parapatellar Arthrotomy for total Knee replacement

Submission date 21/11/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 22/11/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/10/2022	Condition category Surgery	<input type="checkbox"/> Individual participant data

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 parapatellar 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

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, femoral osteotomy, open reduction internal fixation (ORIF) for fracture, patellar realignment, patellectomy and open meniscectomy
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