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Efficacy and cost effectiveness of day surgery for knee replacement: a randomised controlled trial

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
15/05/2009

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SEO193

Study information

Scientific Title

Study objectives
To examine the difference in outcome and cost effectiveness between patients undergoing Unicompartmental knee arthroplasty (UKA) using an accelerated protocol (pain management, physiotherapy advice and discharge within 24 hours) and standard protocol (inpatient physiotherapy & discharge at 6-10 days).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Musculoskeletal diseases: Arthritis (rheumatoid and osteo)

Interventions
Accelerated recovery protocol versus standard management.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

1. Oxford Knee Score, American Knee Society Score, pain, complications, range of movement, function
2. Patient satisfaction at 6 months
3. EuroQol quality of life questionnaire to examine cost effectiveness

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/2000

Completion date
01/11/2002

Eligibility

Key inclusion criteria
1. 40 patients with unicompartmental degenerative knee joint disease undergoing unicompartmental knee arthroplasty (UKA).
2. Unicompartmental degenerative knee joint disease
3. Good anaesthetic risk
4. Tolerance to nonsteroidal anti-inflammatory drugs (NSAIDs)
5. Appropriate social circumstances (for early discharge)
6. Within 45 min travel of Oxford

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Likely to require total knee replacement (TKR)
2. Poor general health
3. Poor understanding of procedure
4. Apprehensive/nervous disposition
5. Severe anaesthetic risk
6. Unable to tolerate large doses of NSAIDs
7. Severe problems on contralateral limb
8. Unable to use crutches
9. Unsuitable social circumstances
10. Geographically inaccessible

Date of first enrolment

01/11/2000

Date of final enrolment
01/11/2002

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nuffield Orthopaedic Centre
Oxford
United Kingdom
OX3 7LD

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive South East (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

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	results	01/10/2005		Yes	No