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

Submission date	Recruitment status	Prospectively registered		
23/01/2004	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
23/01/2004	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
15/05/2009	Musculoskeletal Diseases			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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