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An investigation to compare analgesia from 0.5 mg or 1 mg of intrathecal diamorphine when undergoing total knee replacement surgery

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 06/11/2014	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0247130747

Study information

Scientific Title

Study objectives
Does a higher dose of diamorphine provide better pain relief with fewer side effects?

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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Total knee replacement (TKR) surgery analgesia

Interventions
Prior to total knee replacement surgery, patients will be randomised to:
1. 0.5 mg intrathecal diamorphine
2. 1 mg intrathecal diamorphine

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
10/03/2003

Completion date
31/03/2004

Eligibility

Key inclusion criteria
1. Adult primary total knee replacements
2. Aged 18 - 70 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
10/03/2003

Date of final enrolment
31/03/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

The Great Western Hospital
Swindon
United Kingdom
SN3 6BB

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Swindon and Marlborough NHS Trust (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