ISRCTN28694723 https://doi.org/10.1186/ISRCTN28694723

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
Registration date 30/09/2004	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 06/11/2014	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

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
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

Study type(s)
Treatment

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(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/03/2004

Eligibility

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

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Upper age limit
70 years

Sex
All

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
United Kingdom

England

Study participating centre
The Great Western Hospital
Swindon
United Kingdom
SN3 6BB

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Swindon and Marlborough NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration