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A comparison of intrathecal diamorphine and intravenous morphine for postoperative analgesia in patients undergoing lumbar spinal surgery

Submission date 28/09/2007	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol
Registration date 28/09/2007	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 28/08/2015	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0015187634

Study information

Scientific Title
A comparison of intrathecal diamorphine and intravenous morphine for postoperative analgesia in patients undergoing lumbar spinal surgery

Study objectives
Is intrathecal diamorphine injection an effective method for postoperative analgesia in patients following lumbar spinal surgery?

Updated 28/08/2015: The trial was never started due to lack of suitable participants.

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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Surgery: Analgesia

Interventions
Intrathecal diamorphine vs intravenous morphine

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Diamorphine, morphine

Primary outcome measure
The quality of postoperative analgesia. Patients pain scores will be measured in recovery and on days 1 and 2 postoperatively using a validated pain assessment tool (visual analogue scale 0-100mm). The assessor will be blinded to the patients treatment group. The amounts of morphine required to achieve adequate analgesia via a PCA system will be recorded in both groups.

Secondary outcome measures
Secondary outcome measures include the presence of nausea, vomiting, sedation and pruritis.

Overall study start date
01/01/2006

Completion date
01/04/2007

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
All ASA 1,2 and 3 patients between the ages of 18 to 70 years undergoing lumbar spinal surgery via a posterior surgical approach will be invited to participate in the study.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
70-80 patients

Key exclusion criteria
1. Any contraindications to spinal injection (localised skin sepsis at proposed site of injection, coagulopathy)

2. History of allergy to any of the drugs used in the study
3. Severe hepatic or renal disease

Date of first enrolment
01/01/2006

Date of final enrolment
01/04/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North Cheshire Hospitals NHS Trust
Warrington
United Kingdom
WA5 1QG

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

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.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
North Cheshire Hospitals 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