

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

Contact name

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

70 Years

Sex

All

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

United Kingdom

England

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

Funder(s)

Funder type

Government

Funder Name

North Cheshire Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration