

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	<input type="checkbox"/> Prospectively registered
Registration date 28/09/2007	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 28/08/2015	Condition category Surgery	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Clare Hammell

Contact details

North Cheshire Hospitals NHS Trust
Warrington Hospital
Lovely Lane
Warrington
United Kingdom
WA5 1QG

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