

To compare analgesia and side effects of intrathecal fentanyl and intrathecal morphine

Submission date 02/03/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 27/03/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 16/06/2016	Condition category Musculoskeletal Diseases	<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 Vivienne Ng

Contact details
North wales NHS Trust
Bodelwyddan
Denbighshire
United Kingdom
LL18 5UJ
+44 1745 583910
hyvng@doctors.org.uk

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A randomised controlled trial to compare analgesia and side effects of intrathecal fentanyl and intrathecal morphine

Study objectives

Null hypothesis:

There is no difference in analgesic requirements in patients using 25 mcg fentanyl, 50 mcg morphine or 100 mcg of morphine intrathecally alongside 2.5 ml 0.5% heavy marcaine within the first 24 hours post operation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

To be submitted to the North Wales (Central) Research Ethics Committee in March 2009 (ref: 09 /WNo02/6).

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Analgesia and anaesthesia in orthopaedic surgery

Interventions

The 90 patients will be randomised into 3 groups. The first group will be given 2.5 ml of heavy bupivacaine 0.5% with 25 mcg of fentanyl intrathecally, the second group will be given 2.5 ml of heavy bupivacaine 0.5% with 50 mcg of morphine intrathecally and the last group will be given 2.5 ml of heavy bupivacaine 0.5% with 100 mcg of morphine intrathecally.

To minimise operator factors, there will be one anaesthetist performing the anaesthesia. Intraoperatively, patients will be given 1 g paracetamol (intravenous).

The usage of vasopressors and fluids intraoperatively will be noted. Patients are observed postoperatively in high care and the usage of patient controlled analgesia (PCA) morphine as well as respiratory rates and other side effects will be monitored closely. Patients are only given paracetamol (intravenous) 1 g four times a day (qds) in the first 24 hours as well as the morphine PCA.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Fentanyl, morphine

Primary outcome(s)

Analgesic usage in first 24 hours.

Key secondary outcome(s)

The following will be monitored for the first 24 hours:

1. Vasopressors usage
2. Blood pressure (BP)
3. Respiratory rates
4. Side effects

Completion date

30/04/2010

Eligibility

Key inclusion criteria

1. Both males and females, aged 18-100
2. American Society of Anesthesiologists (ASA) 1 and 2
3. Patients planned for an elective orthopaedic surgery needing spinal anaesthetic as part of routine anaesthetic management

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

100 years

Sex

All

Key exclusion criteria

1. Children <18 years old
2. Pregnant women
3. Patients with contraindications to spinal anaesthetic
4. Patients unable to give informed consent

Date of first enrolment

01/05/2009

Date of final enrolment

30/04/2010

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre

North wales NHS Trust

Denbighshire

United Kingdom

LL18 5UJ

Sponsor information

Organisation

North Wales NHS Trust (UK)

ROR

<https://ror.org/04a496k07>

Funder(s)

Funder type

Government

Funder Name

North Wales NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration