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

Submission date	Recruitment status	[X] Prospectively registered
02/03/2009	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
27/03/2009	Completed	Results
Last Edited	Condition category	Individual participant data
16/06/2016	Musculoskeletal Diseases	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

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# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

# Secondary study design

Randomised controlled trial

# Study setting(s)

Hospital

# Study type(s)

Treatment

# Participant information sheet

Not available in web format, please email ngvivienne@cd-tr.wales.nhs.uk to request a patient information sheet

# 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 measure

Analgesic usage in first 24 hours.

# Secondary outcome measures

The following will be monitored for the first 24 hours:

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

# Overall study start date

01/05/2009

# 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** 

# Age group

Adult

## Lower age limit

18 Years

# Upper age limit

100 Years

#### Sex

Both

# Target number of participants

90

# 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)

### Sponsor details

Bodelwyddan Denbighshire Wales United Kingdom LL18 5UJ +44 (0)1745 583910 ngvivienne@cd-tr.wales.nhs.uk

# Sponsor type

Hospital/treatment centre

#### Website

http://www.wales.nhs.uk/sites3/home.cfm?orgid=802

### ROR

https://ror.org/04a496k07

# Funder(s)

# Funder type

Government

#### Funder Name

North Wales 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