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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

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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
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+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