ISRCTN44947124 https://doi.org/10.1186/ISRCTN44947124

To compare dose and concentration of local anaesthetics in regional anaesthesia

Submission date 02/03/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 27/03/2009	**Overall study status** Completed	
Last Edited 14/06/2016	**Condition category** Signs and Symptoms	

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
Comparison of dose and concentration of local anaesthetics in femoral sciatic block: a randomised controlled trial

Study objectives
Null hypothesis: There is no difference in volume and concentration of local anaesthetics used in the sciatic component of a femoral sciatic block as long as the total dose is constant.

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 /WNo02/7) as of 02/03/2009.

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
Analgesic in regional anaesthesia

Interventions
The 40 patients will be randomised into 2 groups:

The first group will be given 20 ml of levobupivacaine 02.5% with 20 ml of lidocaine 1% for each block.

The second group will be given 20 ml of levobupivacaine 02.5% with 20 ml of lidocaine 1% for the femoral block and 10 ml of levobupivacaine 0.5% with 10 ml of lidocaine 2% for the sciatic block.

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

Patients are observed postoperatively in high care and the usage of PCA morphine as well as side effects will be monitored closely. Patients are only given paracetamol 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)
Levobupivacaine, lidocaine

Primary outcome measure
Analgesia usage within the first 24 hours.

Secondary outcome measures
1. Side effects
2. Motor blockade

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 undergoing femoral sciatic blocks for elective orthopaedic surgery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
40

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
Anaesthetics Department
Denbighshire
United Kingdom
LL18 5UJ

Sponsor information

Organisation
North Wales NHS Trust (UK)

Sponsor details
Bodelwyddan
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+44 (0)1745 583910
Lona.tudorjones@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