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Hyperbaric intra-thecal ropivacaine - a comparison with hyperbaric bupivacaine with respect to extent and duration of motor block

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 23/04/2015	**Condition category** Surgery	

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
N0504163841

Study information

Scientific Title
Hyperbaric intra-thecal ropivacaine - a comparison with hyperbaric bupivacaine with respect to extent and duration of motor block

Study objectives
1. Does intra-thecal hyperbaric ropivacaine result in motor block of shorter duration when compared with an equal dose of bupivacaine (of equal baricity and concentration)?
2. Furthermore, does intra-thecal hyperbaric ropivacaine produce a sensory block of similar extent and duration to an equal dose of intra-thecal bupivacaine of equal baricity and concentration?

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)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Anaesthesia

Interventions
40 patients undergoing spinal anaethesia would be recruited to our study and randomised to receive equal hyperbaric doses of either 0.5% bupivacaine in 8% glucose solution or 0.5% ropivacaine in 8% glucose solution. The solutions would be of similar anaesthesia under standardised conditions, we would measure a number of parameters of particular interest. After surgery, we would study the recovery profile of all recruited subjects for the duration of time taken to achieve complete neurological recovery. We would record strength of dorsi-flexion in 15 minute intervals and time to regression of sensory block.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Ropivacaine, bupivacaine

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/05/2005

Completion date
01/05/2006

Eligibility

Key inclusion criteria
1. Elective surgery
2. Patient and surgery appropriate for spinal anaesthesia
3. ASA grade <3
4. Age >18 years
5. Non-pregnant
6. No known sensitivities to amide class of local anaesthetics
7. Not currently or recently (<3 months) recruited to other clinical trials

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/05/2005

Date of final enrolment
01/05/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wansbeck General Hospital
Ashington
United Kingdom
NE63 9JJ

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 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
Northumbria Healthcare 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