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A comparison of equal volumes of a mixture of 0.5% Bupivacaine (+ adrenaline 1:200,000) with 1% Lignocaine; and 0.375% Ropivacaine for Axillary Brachial Plexus Anaesthesia

Submission date
30/09/2004

Recruitment status
No longer recruiting

Registration date
30/09/2004

Overall study status
Completed

Last Edited
25/11/2013

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

Protocol serial number
N0355135209

Study information

Scientific Title

Study objectives
1. To ascertain whether the combined mixture of equal volumes of 0.5% Bupivacaine (+ Adrenaline 1:200,000) and 1% Lignocaine leads to a clinically superior block, when compared to 0.375% Ropivacaine.
2. Does the mixture have a similar onset of action (OOA), duration of action (DOA), Surgical and Anaesthetic satisfaction, and patient satisfaction when compared to Ropivacaine?

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

Study type(s)
Not Specified

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

Interventions
The patients will be randomly assigned to one of two groups:

GROUP M will receive the mixture of 0.5% Bupivacaine (+ Adrenaline 1:200,000), 20 ml, with 1% lignocaine 30 ml (400 mg total).

GROUP R will receive 0.375% Ropivacaine, 50 ml (187.5 mg total).

A blind observer then will assess sensory and motor block. The sensory block assessment in keeping with previous research will be performed with a short beveled, 23-gauge needle in the innervation areas of the median n. radial n. ulnar n. and musculocutaneous n. and compared to the opposite side. (0 = no block, 1 = loss of sensation to pinprick, 2 = loss of sensation to touch). The degree of motor block will be tested by thumb abduction (radial n), thumb adduction (ulnar n), thumb opposition (median n.) and flexion of the elbow in supination and pronation of the forearm (musculocutaneous n.). (0 = no block, 1 = partial motor block, 2 = complete motor block). The assessment of the sensory and motor block will be made at 5, 10, 15, 20, 30 and 40 min intervals following the completion of the local anaesthetic (LA) injection. It will also continue at 60 min intervals following the cessation of surgery, until either the block has disappeared or the time is midnight and the patient will need to sleep. The time needed for each patient to be ready for surgery (= a grade 1 block for both sensory and motor testing in all areas) will also be recorded. Surgery will be able to start if either pinprick testing reveals analgesia in all areas, or at 50 min if the region to be operated on is adequately analgesed. If adequate analgesia does not occur by 50 min, the block may be supplemented with a peripheral local infiltration of 1% Lignocaine by the Surgeon. Should the block still not be adequate, then the patients will receive a general anaesthetic and be excluded from the trial. Intra-operatively, if the patient feels any discomfort, further sedation and intravenous (iv) fentanyl will be

administered and recorded. Also, any iv analgesia in the 24/24 period following surgery will be recorded. At the end of surgery, it is proposed that the Surgeon and Anaesthetist will independently assess the overall quality of the block on a three point scale for both analgesia and muscle relaxation. (0 = unsatisfactory, 1 = satisfactory, 2 = excellent). In addition, the patients will be asked by an observer (unaware of group assignment) to give a score of the quality of there own analgesia as they perceived it. (0 = poor, 1 = sufficient, 2= excellent).

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome(s)
Degree and quality of local anaesthetic blocks in two groups of patients.

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/05/2004

Eligibility

Key inclusion criteria
1. American Society of Anesthesiologists (ASA) I - III
2. Age above 16 years, weight between 60 - 100 kg and height above 150 cm

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

Key exclusion criteria
1. Pre-existing neurological, cardiovascular, lymphatic and hepatic conditions
2. Psychiatric disease, alcohol or drug abuse
3. Allergy or other reactions to LA
4. Age <16 or >75, weight <60 kg or >100 kg
5. Pregnancy
6. Procedures where postoperative bandaging would significantly interfere with the researchers neurological assessment

Date of first enrolment

01/02/2004

Date of final enrolment
31/05/2004

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Mid Essex Hospital Services NHS Trust (BH)
Chelmsford
United Kingdom
CM1 7ET

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Mid Essex Hospital Services NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration