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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 25/11/2013	**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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure
Degree and quality of local anaesthetic blocks in two groups of patients.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/2004

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

Age group
Adult

Sex
Not Specified

Target number of participants
Not provided at time of registration

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
England

United Kingdom

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

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

Website
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Funder(s)

Funder type
Government

Funder Name
Mid Essex Hospital Services 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