

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	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/11/2013	Condition category Surgery	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Sandip Pal

Contact details

Mid Essex Hospital Services NHS Trust (BH)
Broomfield Hospital
Chelmsford
United Kingdom
CM1 7ET

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

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

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