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ED95 bupivacaine and supraclavicular block

Submission date	Recruitment status	[_] Prospectively registered
29/04/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/07/2013	Surgery	

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
7925

Study information

Scientific Title
What is the ED95 dose for bupivacaine for supraclavicular brachial plexus block using ultrasound?

Study objectives
To determine the ED95 dose for 0.5% bupivacaine for supraclavicular brachial plexus block using ultrasound.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds (East) Research Ethics Committee approved on the 2nd November 2009 (ref: 09/H1306 /98). Amendment approved on the 22nd February 2010.

Study design
Non-randomised interventional trial

Primary study design
Interventional

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Topic: Generic Health Relevance and Cross Cutting Themes; Subtopic: Generic Health Relevance (all Subtopics); Disease: Anaesthetics

Interventions
Primary outcome is the success or failure of the supraclavicular block. This will be assessed by testing the patient's ability to detect cold sensation by application of a cold alcohol swab to the skin. This will be measured by asking the patient to score the cold sensation from 0 - 10. Any score higher than 0 will be deemed an unsuccessful block. This assessment will be carried out at 15 minute intervals for upto 45 minutes after the block has been performed. There will be no follow up after this.

Intervention Type
Procedure/Surgery

Phase
Phase IV

Primary outcome(s)
Ability to detect cold sensation by application of cold alcohol swab to the skin at the sensory dermatomes of the median, ulnar, radial and musculocutaneous nerves in the upper limb, measured 45 minutes after performing the supraclavicular block.

Key secondary outcome(s))
No secondary outcome measures

Completion date
04/10/2010

Eligibility

Key inclusion criteria
1. American Society of Anaesthesiologists (ASA) 1 - 3 patients
2. Aged greater than 18 years, either sex
3. Routine hand, forearm or upper limb surgery

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. ASA greater than 3
2. Aged less than 18 years
3. Allergy to bupivacaine
4. Unable to give written informed consent
5. Body Mass Index greater than 35 kg/m^2
6. Pregnant women

Date of first enrolment
05/10/2009

Date of final enrolment
04/10/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Beckett Street
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
University of Leeds (UK)

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
National Institute for Academic Anaesthesia (UK)

Alternative Name(s)
NIAA

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2013		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes