

ED95 bupivacaine and supraclavicular block

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

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.

Primary study design

Interventional

Study design

Non-randomised interventional trial

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/m²
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)

The National Institute of Academic Anaesthesia (NIAA), 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