# ED95 bupivacaine and supraclavicular block

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

### Plain English summary of protocol

Not provided at time of registration

### Contact information

### Type(s)

Scientific

#### Contact name

**Prof Phil Hopkins** 

#### Contact details

Beckett Street Leeds United Kingdom LS9 7TF

### 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             |