

ED95 bupivacaine and supraclavicular block

Submission date 29/04/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/04/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/07/2013	Condition category Surgery	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Not Specified

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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.

Secondary outcome measures

No secondary outcome measures

Overall study start date

05/10/2009

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 40

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

England

United Kingdom

Study participating centre

Beckett Street

Leeds

United Kingdom

LS9 7TF

Sponsor information

Organisation

University of Leeds (UK)

Sponsor details

Academic Department of Rehabilitation Medicine

Woodhouse Lane

Leeds

England

United Kingdom

LS2 9JT

neville.young@leedsth.nhs.uk

Sponsor type

University/education

Website

<http://www.leeds.ac.uk/>

ROR

<https://ror.org/024mrx33>

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

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

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