

# Ultrasound-guided supraclavicular brachial plexus block versus intravenous regional anaesthesia for the manipulation of fractures of the distal radius

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<b>Registration date</b> 31/08/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/04/2017	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<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

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

V 2.0

## Study information

### Scientific Title

Ultrasound-guided supraclavicular brachial plexus block versus intravenous regional anaesthesia for the manipulation of fractures of the distal radius: a randomised controlled trial

### Acronym

SCivi

### Study objectives

Is ultrasound-guided brachial plexus block equivalent to intravenous regional anaesthesia in providing pain relief for the manipulation of fractures of the distal radius?

### 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)

Hospital

### Study type(s)

Treatment

### Participant information sheet

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

### Health condition(s) or problem(s) studied

Distal radius fractures

### Interventions

Intravenous regional anaesthesia:

An intravenous cannula will be placed in the dorsum of the hand of the affected limb and a second cannula placed in the contralateral limb. A suitably sized double cuff tourniquet will be placed around the upper arm over a layer of orthopaedic wool. The limb will be elevated for two minutes and the tourniquet inflated to 80 mmHg above the systolic blood pressure. Following confirmation of the absence of a radial pulse and capillary refill in the fingers the dose of 0.5%

prilocaine will be injected via the cannula in the dorsum of the affected hand. The volume injected will be 40 ml for patients weighing less than 70 kg and 50 ml for those 70 kg and over. Once anaesthesia has been confirmed by the absence of pin-prick sensation as outlined below, the manipulation will be performed. The tourniquet will remain inflated for a minimum of 20 minutes from the time of injection.

#### Supraclavicular brachial plexus block:

The intervention group will undergo an ultrasound-guided brachial plexus block using the following technique: an intravenous cannula will be placed in the non-affected hand. The block will be performed using a sterile technique (sterile gloves, chlorhexidine spray, sterile probe cover). Visualisation of the brachial plexus will be undertaken with a Siemens Acuson X300 ultrasound machine with 10 MHz linear array probe. A view of the subclavian artery and surrounding nerve trunks will be obtained with the probe placed in the supraclavicular fossa in the coronal oblique plane. With the patient supine and the head turned at 45 degrees away from the probe. 1 ml of 1% lignocaine will be infiltrated in the skin at the injection site. A 22 gauge 50 mm short bevelled insulated block needle (Braun, Stimuplex) will be inserted at the lateral edge of the probe. The needle will be guided under direct vision from lateral to medial along the long axis of the probe using an in-plane approach. A total of 20 ml of 1% prilocaine will be injected around the trunks with frequent aspiration to exclude inadvertent intravascular needle placement. Spread of local anaesthetic will be observed in real time. Injection will be into at least two separate areas around the nerve trunks.

Duration will be around 1 hour in total for each intervention. Total duration of follow-up will be until seen in fracture clinic. This will be approximately 3 to 7 days in both arms.

#### **Intervention Type**

Other

#### **Phase**

Not Applicable

#### **Primary outcome measure**

1. Degree of pain experienced by the patient during manipulation, assessed by a Visual Analogue Scale (VAS) score
2. Overall satisfaction with procedure, assessed by a Visual Analogue Scale (VAS) score
3. Duration from randomisation to completion of the manipulation

Assessed at the end of the manipulation of the fracture, i.e. approximately one hour after entering the trial.

#### **Secondary outcome measures**

1. Number of manipulations required
2. Emergency department (ED) length of stay
3. Time from commencing the procedure until discharge
4. Need for subsequent surgical intervention

Assessed at 3 - 7 days.

#### **Overall study start date**

01/10/2010

**Completion date**

01/10/2011

## Eligibility

**Key inclusion criteria**

1. Aged greater than or equal to 18 years, either sex
2. Closed fracture of the distal third of the radius
3. Manipulation of the fracture required in the emergency department as judged by an emergency department middle grade doctor or consultant

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

68

**Key exclusion criteria**

1. Confusion (Abbreviated Mental Test [AMT] less than 8)
2. Multiple injuries
3. Pre-existing sensory or motor deficit in the affected limb
4. Allergy to lignocaine or prilocaine
5. Any condition precluding the use of a tourniquet in the affected limb
6. Inability to read English
7. Middle grade doctor or consultant trained in intravenous regional anesthesia (IVRA) and supraclavicular block (SCB) not available
8. Significant pre-existing respiratory impairment (defined as exercise tolerance less than 100 metres on flat ground)
9. Anticoagulation, inherited bleeding disorders or any other known clotting or platelet deficiency or abnormality. The use of anti-platelet medications such as aspirin will not count as a contraindication.

**Date of first enrolment**

01/10/2010

**Date of final enrolment**

01/10/2011

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Barnsley Hospital NHS Foundation Trust**

Barnsley

United Kingdom

S75 2EP

## Sponsor information

**Organisation**

Barnsley Hospital NHS Foundation Trust (UK)

**Sponsor details**

Gawber Road

Barnsley

England

United Kingdom

S75 2EP

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.barnsleyhospital.nhs.uk/>

**ROR**

<https://ror.org/00yx91b22>

## Funder(s)

**Funder type**

Government

**Funder Name**

Barnsley Hospital NHS Foundation 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