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

Submission date 28/05/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 31/08/2010	**Overall study status** Completed	
Last Edited 18/04/2017	**Condition category** Injury, Occupational Diseases, Poisoning	

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 fracutres 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 brachical 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
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England
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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