Ultrasound guided axillary nerve block compared to hematoma block for analgesia in patients with closed reposition of distal forearm fractures.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint injuries
Study type	Interventional

Summary

ID

NL-OMON50895

Source
ToetsingOnline

Brief title
USANB trial

Condition

- Bone and joint injuries
- Nervous system, skull and spine therapeutic procedures

Synonym
Distal forearme fracture; wrist fracture

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Eventuele additionele kosten worden ondervangen door vakgroep SEH.

Intervention

Keyword: Axillaire nerve block, Distal forearme fracture, Emergency Department, Ultrasound guided peripheral nerve block

Outcome measures

Primary outcome

The primary endpoint of this study is pain reduction on a NRS scale.

Pain scores using an 11-step numeric rating scale (NRS) ranging from 0 (no

pain) to 10 (worst pain imaginable) on different times:

o Before application of ANB or FHB.

o During the application of ANB or FHB.

o During reposition

Secondary outcome

Secondary study parameters/endpoints

- Total procedural time in minutes from onset of the procedure (FHB or AB)

until end of the first reposition.

- Complications

- Dosage of used anaesthetic

- Satisfaction of the physician performing reposition measured on a NRS scale.

- Satisfaction of the physician performing the ANB or FHB, measured on a NRS

scale.

- Patients* satisfactory measured on a NRS scale

- Number of attempts for correct injection and positioning

Other study parameters

- Side of fracture (left/right)

- Type of fracture (radius and/or ulna; angulation to volar/dorsal;

intra-articular/extra-articular; multi-fragmentary.

- Date of trauma (date)

- Date of reposition (date)

- Age (in years)

- Weight (in kg)

- Height (in cm)

- BMI (underweight <18.5; normal 18.5-24.9; overweight 25-29.9; moderate

obesity 30-34.9; severe obesity 35-39.5; morbid obesity >40)

- Gender (m/f)

- Osteoporosis (yes/no)

- Prior fracture of same side (yes/no)

- Precise amount and type of local anaesthesia used (mg/kg)

- Type and amount of supplementary analgesics (type and dose)

- Usage of any pain medication administrated prior for intervention for pain

due to fracture (type and dose)

Study description

Background summary

Fractures of the forearm are very commonly seen in the Emergency Department (ED) and mostly comprise the distal radius and ulna. Distal forearm fractures have an incidence of 278 per 100.000 patient years. Court-Brown found a incidence of distal radius fractures of 195 per 100.000 patients. Distal radius fractures alone account for 17.5-46% of all skeletal fractures observed in primary care setting. And as distal radius fractures are considered as an osteoporotic fracture, the incidence will increase with our ageing population. The majority of distal radius fractures are treated conservatively (non-operatively). However, up to half of these conservatively treated fractures require closed reposition for better union and functional outcome. This is a painful procedure and adequate pain management is of utmost importance, both for reducing pain as well as achieving optimal clinical outcome.

There are several interventions for pain management in these patients, amongst which general anaesthesia, procedural sedation and analgesia, intravenous regional anaesthesia, peripheral nerve block (PNB) or local analgesia such as the fracture haematoma block (FHB)). Of these, the latter is most commonly used in the ED and is advised by the current Dutch trauma guideline. Interestingly, whether or not this is the superior method is still unknown due to scarcity of scientific evidence. However, the FHB is known to be a painful procedure, with unsatisfactory success rates (a mean visual analogue scale (VAS) of 5.53 (SD 3.67)) and with outcomes very dependent of the individual physicians* skills. Other options such as procedural sedation and analgesia (PSA) or general anaesthesia are time-consuming procedures, require expensive resources, and poses unnecessary risks to the patient such as hypotension or hypoxia. Since the use of ultrasound in EDs is more and more available, ultrasound-guided peripheral nerve blocks for pain control are a realistic and safer option. A recent study comparing ultrasound-guided peripheral nerve blocks (cubital nerve block (CNB) and axillary nerve block (ANB)) with FHB found significant reduction in pain perception, especially in the ANB block. However, this study did not investigate some important secondary factors in an ED such as procedural time, reposition time, re-reposition, quality of reposition and other resources as personal and financial costs. Feasibility studies for ANB showed a short time for procedure performance (only 5 minutes) and time to achievement of analgesia comparable to FHB, indicating good applicability in the busy ED. Moreover, ANB does not pose patients to a great complication risk whereas complications such as infection, local nerve injury and local analgesic systemic toxicity (LAST)) are rare. This especially after the introduction of ultrasound guidance of peripheral nerve blocks. Most complications are minor and consist of soreness at injection site and transient numbness, as comparable with complications seen in FHB and may even be less due to the use of ultrasound guidance. Furthermore, performing a cubital nerve block (CNB) involves multiple injections whereas ANB could be performed using a single injection.

Compared to the more proximal nerve blocks, for example the supraclavicular brachial plexus and interscalene block, complications such as the risk of pneumothorax, phrenic nerve paralysis and Horner*s syndrome do not exist

performing an ANB. Compared to the *blindly* performed FHB block, the risk for an intravascular injection is small, due to the visualisation of the tip of the needle using ultrasound guidance. Moreover, the injection site is not painful prior to the procedure due to the existing fracture. Lastly, using a PNB leads to a better muscle relaxation due to motor loss of distal muscles, increasing the treatment process and results.

Study objective

The primary goal of this study is to compare ultrasound-guided ANB with FHB for analgesia during closed reposition of distal forearm fractures. Secondary goals are evaluation of feasibility in the ED regarding time and procedure success rate.

Primary Objective:
The primary objective of this study is to compare ultrasound-guided ANB with FHB for analgesia during reposition of non-operatively treated forearm fractures.

Hypothesis:
We hypothesize that ultrasound guided ANB will lead to a clinically significant pain reduction (>= 2 point reduction on a NRS 0-10 scale) and improve analgesia to reposition distal forearm fractures compared to the standard FHB.

Secondary Objectives:
Secondary objectives will be used to evaluate the feasibility in the ED and consists of procedural time and number of attempts for a successful block.

Study design

This study is a randomised controlled prospective study performed in the ED of a teaching hospital (MCL Leeuwarden, Trauma Centre Level II).

Intervention

A patient with a distal forearm fracture who meets the inclusion and exclusion criteria will be randomized and allocated to the FHB or ANB group.
The FHB will be performed without ultrasound, as is common practice. The ANB will be performed using ultrasound, as is common practise:

FHB block procedure
In this blinded technique (as is common practise), after disinfection, the needle is inserted from the dorsal side to the bone surface and the physician will search for the fractured area. Then blood is aspired in the cannula as a sign of the needle tip being in the haematoma surrounding the fracture, and the anaesthetic 1% lidocaine is injected.

ANB block procedure
After the arm is positioned in a comfortable position, the medial upper arm is disinfected.
Using a linear probe and sterile ultrasound gel, the anatomic landmarks as the axillary artery and the nerves are identified, as taught by training of an experienced anaesthesiologist. Then, the anaesthetic, 1% lidocaine, is being injected around the identified nerves. An ANB consist of blocking the radial, median and ulnar nerve and the musculocutaneous nerve. This can be achieved by a single injection through the skin. It will result in anaesthesia of the mid-arm to and including the hand. Some emergency physicians are already practising this technique, some are not. All will be additionally trained.

Study burden and risks

Regardless of a patient being treated within in our study, fracture reposition might be necessary as is analgesia prior to this reposition. Both the FHB and the ultrasound guided ANB are well established methods of analgesia, and used as common practise. Also lidocaine is well established as a local anaesthetic agent, used as common practise. Therefore no significant ethical concerns are found with conduction of the study.
Participants have the possible benefit of a ANB because of possible better pain reduction, the use of less local anaesthetics (and lesser risk for local analgesic systemic toxicity (LAST), and the fact that not a wounded area but a healthy part is anesthetised (better analgesia and less risk of infection). To our knowledge there are no long-term benefits from participation. The gain for future patients in the potentially increased pain relief satisfaction far outweighs the minimal disadvantages of study participation including as a couple additional questions and maybe some soreness on the infection site on the upper arm.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients in the ED with a X-ray confirmed dislocated distal forearm fracture.
Patients >= 16 years of age who are sufficient capable to decise about important medical issues.
Patients who have adequate knowledge and understanding of the Dutch language.

Exclusion criteria

Open fractures requiring surgery
Multi-trauma patients
Inability to give informed consent
Abnormal neurovascular examination requiring immediate reposition or surgery
Allergy for lidocaine

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2021
Enrollment:	118
Type:	Actual

Ethics review

Approved WMO

Date:	22-03-2021
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL75603.099.20

Study results

Date completed:	27-11-2023
Actual enrolment:	117