Axillary and Cubital Ultrasound Guided Nerve Blocks in Distal Radius Fractures, a RCT

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON42984

Source
ToetsingOnline

Brief title
Peripheral nerve blocks for radius fractures

Condition

- Fractures

Synonym
Distal radius fractures, wrist fractures

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: Vakgroep Orthopedie

Intervention

Keyword: Axillary nerve block, Cubital nerve block, Distal radius fracture, Ultrasound guided

Outcome measures

Primary outcome

The primary objectives of this study are to investigate whether axillary nerve block leads to a decrease in pain compared to control patients. This will be measured through a raw pain intensity difference (PID) using visual analogue pain score after fracture reduction.

Secondary outcome

The secondary parameters of this study includes pain measured in rest, during physical examination, after the analgesia procedure, after fracture reduction, after plaster cast application, after control radiograph, secondary loss of reduction measured on plain radiographs.

Study description

Background summary

Distal radius fractures are commonly diagnosed in emergency departments. These fractures are often treated conservatively through fracture reduction and cast immobilization. Pain reduction during this procedure is achieved through injection of a local anaesthetic into the fracture hematoma. Recently, we showed that a peripheral nerve block around the elbow provides more superior analgesia compared to the standard hematoma block However, these patients were still not pain free. Possibly, this results of inadequate treatment of the musculocutaneous nerve. We therefore propose to study the effect of a axillary nerve block after a distal radius fracture compared to the cubital nerve block.

Study objective

The objective of this study is to determine the clinical outcomes of ultrasound guided axillary nerve block using prilocaine, in patients with distal radius

fractures and compare these results to patients treated with a ultrasound guided cubital nerve block.

Study design

Patients admitted to the Reinier de Graaf Hospital*s emergency department with radiographic proven distal radius fracture in need of reduction, will be included in this randomized controlled trial. Participants will be randomized into one of two arms: cubital nerve block with prilocaine or axillary nerve block with prilocaine. Patient will be included into the study immediately after radiographic confirmation of the distal radius fracture in need of reduction.

Intervention

The study group will receive a axillary nerve block using 30ml (300 mg) prilocaine. The control group will receive a cubital nerve block using 20ml (200 mg) prilocaine.

Study burden and risks

Our previous study concluded that a cubital nerve block provokes less pain in distal radius fracture reduction. Since the musculocutaneous nerve is not anaesthetized with this technique, patients treated with axillary nerve block are likely to suffer even less pain, and as a result might have a more optimal outcome in fracture healing as well. Patients included in this study will risk complications associated with cubital or axillary nerve blockage. These complication rates are low and usually self-limiting in the first days. Possibly, patients in the intervention group might show reduced numbers of chronic regional pain syndrome (CRPS) development. The number of out-patient clinic visits is the same as for non-participating patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Proven dislocated distal radius (simple or multifragmentary, intra-articular or extra-articular fractures) requiring closed reduction
Normal upper extremity anatomy and neurovascular examination
Aged 18-years or older
Patients eligible for primary surgical fracture fixation

Exclusion criteria

Inability to perform the NRS for pain (eg due to delirium, or cognitive impairment)
No good understanding of the Dutch language
Multi-trauma patients
Hypersensitivity to prilocaine and/or PABA (preservative agent in Citanest)
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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):	24-01-2017
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	22-12-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	22-01-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL59513.098.16