

A prospective randomized trial comparing the effect of two different methods of anesthesia for reduction of displaced distal radius fractures; haematoma block versus peripheral nerve block at the elbow

Published: 23-05-2013

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To compare the effect of two different methods of anesthesia on painsensation (VAS score) during fracture reduction.

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

Summary

ID

NL-OMON44947

Source

ToetsingOnline

Brief title

Reduction of distal radius fracture: regional nerve block or hematoma block

Condition

- Bone and joint therapeutic procedures

Synonym

displaced distal radius fracture; displaced wrist fracture

Research involving

Human

Sponsors and support

Primary sponsor: Heelkunde

Source(s) of monetary or material Support: geen

Intervention

Keyword: Anesthesia, Distal radius fracture, Haematoma block, Regional nerve block elbow

Outcome measures

Primary outcome

Pain during fracture reduction (VAS score)

Secondary outcome

Complications

Secondary re-dislocation

Study description

Background summary

Fracture of the distal radius is a common clinical problem, particularly in older white women with osteoporosis. For patients with a displaced distal radius fracture, fracture reduction is the first step in management of these injuries. Anaesthesia is usually provided during reduction of displaced fractures; different methods of anesthesia are used in clinical practice. Current literature offers no strong evidence to support either of the different techniques (general anesthesia excluded) in providing best analgesia during fracture reduction. We think that regional nerve block at the elbow provides equal or better analgesia compared to haematoma block anesthesia.

Study objective

To compare the effect of two different methods of anesthesia on painsensation (VAS score) during fracture reduction.

Study design

A prospective randomised controlled trial, comparing two different methods of

anesthesia

Intervention

Two different methods of anesthesia (no general anesthesia): local anesthesia with haematoma block around the fracture or regional nerve blocking anesthesia at the level of the elbow

Study burden and risks

The two different intervention methods of anesthesia within this study are both used in general practice. Haematoma block could cause a headache which will disappear in time. Regional nerve blocking in the elbow could cause a headache as well when the anesthetic material is injected in an arterial or venous blood vessel. Theoretically, damage to the nerves is possible if the anesthetic material is injected directly into the nerve. This is unlikely to happen, because patients will feel pain or strange feeling in their fingers when the needle enters the nerve; the doctor will change the position of the needle before injection of the anesthetic material.

Patients in this study will not visit the hospital more frequently than patients who are not participating within this study. The outpatient control moment after one week could take 5 minutes more of the patient's time. Also, the doctor will call the patient once to ask for pain sensation at that moment. The regular management of the wrist fracture does not change by participating within this study.

Contacts

Public

Selecteer

Bronovolaan 5
Den Haag 2597 AX
NL

Scientific

Selecteer

Bronovolaan 5
Den Haag 2597 AX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients > 18 years old

Displaced distal radius fractures

Closed fractures

Informed consent

Exclusion criteria

Children

Fractures > 7 days old

Open fractures

Bilateral fractures

Poly-trauma patients

Expected noncompliance

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):	20-08-2014
Enrollment:	38
Type:	Actual

Ethics review

Approved WMO	
Date:	23-05-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO	
Date:	09-01-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO	
Date:	11-03-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO	
Date:	14-12-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO
Date: 31-08-2017
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

ID: 24465

Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL42831.098.12
OMON	NL-OMON24465