# Ultrasound guided cubital nerve blockage in distal radius fractures, an RCT.

Published: 29-04-2016
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The objective of this study is to determine the clinical outcomes of ultrasound guided cubital nerve blockage using prilocaine, in patients with distal radius fractures and compare these results to patients treated with a fracture hematoma block.

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

## Summary

### ID

NL-OMON43389

**Source**
ToetsingOnline

**Brief title**
Cubital PNBs for distal radius fractures

### Condition

- Fractures

**Synonym**
Forearm fracture;

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Reinier de Graaf Groep
**Source(s) of monetary or material Support:** vakgroep orthopedie RdGG

## Intervention

**Keyword:** distal radius fracture, peripheral nerve block, ultrasound guided

## Outcome measures

### Primary outcome

The primary objectives of this study are to investigate whether cubital nerve blockage 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 after the analgesia procedure, after fracture reduction, 15 and 30 minutes after reduction, need for re-reduction, secondary loss of reduction measured on plain radiographs. 1,4 and 12 weeks after fracture reduction, the patient will visit the outpatient clinic (standard care).

# 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. However, the extent of functional pain management of this technique remains arguable. We therefore propose to study the effect of a cubital nerve block after a distal radius fracture compared to a conventional fracture hematoma block.

### Study objective

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

fractures and compare these results to patients treated with a fracture hematoma 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 single-blinded randomized controlled trial. Participants will be randomized into one of two arms: cubital nerve block with prilocaine or local injection prilocaine into the fracture hematoma. 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 cubital nerve block using 5ml prilocaine. The control group will receive a local injection into the fracture hematoma with 10ml prilocaine.

### Study burden and risks

As suggested in previous studies using Bier*s block, patients treated with cubital nerve blockage are likely to suffer 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 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

Dislocated distal radius fracture in need of closed reduction
Normal anatomy and neurovascular examination upper extremity
Aged 18 years or older

## Exclusion criteria

Cognitive impairment
On-going delirium at inclusion
No good understanding of the Dutch language
Multi-trauma patients
Known hypersensitivity to local anaesthetics

# Study design

## Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 15-05-2016 |
| Enrollment: | 170 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 29-04-2016 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

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| Approved WMO Date: | 22-01-2018 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>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 | NL56606.098.16 |