# Surgical treatment of midshaft clavicular fractures with dislocation: plate fixation versus intramedullary fixation

Published: 19-10-2010 Last updated: 04-05-2024

The aim of this prospective randomized study is to compare results of plate fixation and intramedullary fixation postoperatively after two weeks and after a follow-up period of one year.

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

# Summary

### ID

NL-OMON39026

**Source** ToetsingOnline

**Brief title** The Plate Or Pin study: \*POP\* study

### Condition

• Fractures

**Synonym** broken collarbone, clavicular fracture

**Research involving** Human

### **Sponsors and support**

Primary sponsor: Diakonessenhuis Utrecht Source(s) of monetary or material Support: Ministerie van OC&W

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### Intervention

Keyword: dislocated midshaft clavicular fractures, intramedullary fixation, plate fixation

### **Outcome measures**

#### **Primary outcome**

DASH score 6 months after surgery

#### Secondary outcome

DASH score after one year

function of the shoulder (Constant Score) 6 months after surgery

DASH and Constant scores at 6 weeks and 3 months

complications, both intra-operatively, immediately postoperatively (two weeks),

and in a period of 1 year after surgery.

the number of re-operations related to unsatisfactory results in a period of

one year after surgery

time to radiological consolidation

perception of pain 2 weeks postoperatively

patient satisfaction with the cosmetic result of the treatment 6 months and one

year after surgery.

elective implant removal in a period of one year after surgery

Addendum: scapulothoracic rythm one year postoperatively (pilot study)

# **Study description**

#### **Background summary**

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Historically clavicular fractures were treated conservatively. Consolidation was achieved within a few weeks, even with severe dislocation. However, in the last couple of years poor results (malunion, nonunion and low patient satisfaction scores) were described of conservatively treated dislocated midshaft clavicular fractures (DMCF).

The two most commonly used operative techniques for treatment of DMCF are plate fixation and intramedullary fixation with a Titanium Elastic Nail (TEN). In recently published prospective randomized studies both techniques proved to be superior (better functional results and lower nonunion rates) compared to conservative treatment of DMCF.

However, which technique provides the best results is still unknown. A recent Cochrane review showed that prospective randomized studies comparing surgical treatment of DMCF are lacking.

#### **Study objective**

The aim of this prospective randomized study is to compare results of plate fixation and intramedullary fixation postoperatively after two weeks and after a follow-up period of one year.

#### Study design

prospective randomized multicenter study

#### Intervention

plate fixation or intramedullary fixation with a Titanium Elastic Nail (TEN)

#### Study burden and risks

Risks of surgery for both techniques as described in the protocol.

As previously mentioned both techniques are globally used for surgical treatment of dislocated midshaft clavicular fractures. Traumasurgeons in the three participating hospitals have sufficient experience with both techniques.

The extra effort for participating patient will be the completion of the questionnaires. Treatment and number of outpatient department visits won't be different.

Addendum: In addition to regular follow up in the outpatient clinic 10 patients, 5 from each group, will be asked to perform standard range of motion exercises which are to be recorded on video. Further analysis of scapulothoracic rythm will take place afterwards. This requires approximately 10 minutes of the patients' time without any additional risks for the patients'

health.

# 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**

- 1) Unilateral dislocated midshaft clavicular fracture
- 2) No medical contraindications to general anesthesia
- 3) Provided informed consent

# **Exclusion criteria**

- 1) Age < 18 years or > 65 years
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- 2) Multitrauma patients
- 3) Open fracture
- 4) Pathological fracture
- 5) Fracture > 1 month old
- 6) Neurovascular disorders
- 7) Glasgow Coma Scale <12 (moderate to severe head injury)
- 8) An inability to comply with follow-up (a transient or an inability to read or complete forms)
- 9) Pre-existing shoulder pathology in affected side (such as rotator cuff lesion,
- acromioclavicular pathology or previous shoulder surgery)

# Study design

# Design

Study type: Interventional	
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

# Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2011
Enrollment:	120
Туре:	Actual

# **Ethics review**

Approved WMO Date:	19-10-2010
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	15-02-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United

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	(Nieuwegein)
Approved WMO Date:	08-03-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-07-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	02-04-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

# **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 CCMO

**ID** NL32928.100.10