

# Conservative treatment of midclavicular fractures with Kinesio® clavicular tape and sling vs sling

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON28907

### Source

Nationaal Trial Register

### Brief title

Conclaaf

### Health condition

clavicle, randomized controlled trial, fracture bones, quality of life

## Sponsors and support

**Primary sponsor:** Onze lieve vrouwe gasthuis (OLVG), Amsterdam, the Netherlands

**Source(s) of monetary or material Support:** Onze lieve vrouwe gasthuis (OLVG), Amsterdam, the Netherlands

## Intervention

## Outcome measures

### Primary outcome

Quality of life measured by the DASH (Disabilities of the Arm, Shoulder and Hand ) questionnaire

### **Secondary outcome**

- VAS (visual analogue scale)
- Non-union percentage
- SF-36
- Constant score

## **Study description**

### **Background summary**

Fractures of clavicle are frequently diagnosed. Of all fractures about 4 % are fractures of the clavicle. Of these about 75% are mid-shaft (3% of all fractures). Conservative sling treatment of the mid-shaft fractures dominates the therapeutic approach. Complications encountered with this procedure are mal-union, non-union, pain, restrictions of arm movements and cosmetic. The treatment has an acceptable prognosis with relative little additional morbidity. When focussing on quality of life after sling treatment there are still many complaints of pain, weakness of muscular strength and rapid fatigue of the arm muscles on exertion during the first weeks. A new type of elastic tape, Kinesio® clavicle tape in combination with sling treatment gave remarkable better results in a small pilot set-up. Relief of pain and better shoulder function was immediately experienced by all patients. These effects lasted the first weeks.

Tape treatment has never been compared to sling treatment in a RCT.

### **Study objective**

The hypothesis is that patients who receive treatment with kinesio tape and sling will experience less pain and better shoulder function compared to patients treated with only a sling.

### **Study design**

The study will take 2 years to finish.

### **Intervention**

The experimental group gets the Kinesio® clavicle tape application during 3 weeks in combination with sling treatment. The other group gets the sling treatment in combination with a placebo tape application.

## Contacts

### **Public**

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## Eligibility criteria

### **Inclusion criteria**

1. Patients with a midclavicular fracture
2. In the age from 12 to 60 years
3. With a informed consent

### **Exclusion criteria**

1. Age less than twelve or greater than sixty years
2. A pathological fracture
3. An open fracture
4. A fracture older than 28 days after injury
5. A fracture in the proximal or distal third of the clavicle
6. An associated neurovascular injury with objective neurological findings on physical

examination

7. An inability to comply with the follow-up
8. A lack of consent
9. Good understanding of dutch language by word and in writing
10. The use of psychopharmacological drugs

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-10-2008
Enrollment:	128
Type:	Anticipated

## Ethics review

Not applicable	
Application type:	Not applicable

## 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
NTR-new	NL672
NTR-old	NTR1374
CCMO	NL23237.100.08
ISRCTN	ISRCTN wordt niet meer aangevraagd

## Study results

### Summary results

- Nonoperative treatment compared with plate fixation of displaced midshaft clavicular fractures. A multicenter, randomized clinical trial. J Bone Joint Surg Am 2007b; (89): 1-10. Andersen K, Jensen P O, Lauritzen J. <br>
- Treatment of clavicular fractures. Figure-of-eight bandage versus a simple sling. Acta Orthop Scand 1987; (58): 71-74. Jeray K J.<br>
- Acute midshaft clavicular fracture. J Am Acad Orthop Surg 2007; (15): 239-248. McKee M D, Pedersen E M, Jones C, Stephen D J, Kreder H J, Schemitsch E H, Wild L M, Potter J.<br>
- Deficits following nonoperative treatment of displaced midshaft clavicular fractures. J Bone Joint Surg Am 2006; (88): 35-40. Zlowodzki M, Zelle B A, Cole P A, Jeray K, McKee M D.<br>
- Treatment of acute midshaft clavicle fractures: systematic review of 2144 fractures: on behalf of the Evidence-Based Orthopaedic Trauma Working Group. J Orthop Trauma 2005; (19): 504-507.