

RCT: Conservative treatment of clavicular fractures with kinesio tape or only a sling

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON47952

Source

ToetsingOnline

Brief title

#CAKE

Condition

- Fractures

Synonym

clavicular fracture

Research involving

Human

Sponsors and support

Primary sponsor: Isala Klinieken

Source(s) of monetary or material Support: Isala (uitvoerend ziekenhuis);SEH (eigenlijk zijn er alleen kosten voor de tape)

Intervention

Keyword: Clavicular fracture, Conservative treatment, Kinesio tape

Outcome measures

Primary outcome

The main study parameter is the decrease in NRS between T0 and T1, T2, T3, T4, T5 and T6 between both groups (standard treatment or kinesio tape).

Secondary outcome

Secondary study parameters are:

- Use of analgesics
- Time to return to work/school/sport
- DASH score
- Constant score
- Union/nonunion after 6 weeks

Study description

Background summary

Clavicular fractures are frequently diagnosed fractures on the emergency departments. Fractures of the clavicle or shoulder have an incidence of 115 per 100.000 persons in the Netherlands (1). Operative treatment is performed in some cases, but is associated with more complications, but lower non-union rates (2). However most patients are treated conservative by a sling in combination with analgesics. Besides treatment with a sling there are some different options for conservative treatment. In the past the use of an eight clavicular bandage is investigated in a randomised controlled study (3). The results showed that patients experienced more pain during the first day. There were no statistically differences in satisfaction, return to activities or functional outcome.

In the Netherlands kinesio tape is part of the conservative treatment in some hospitals, however there are no clinical trials about the efficacy of kinesio

tape in patients with a clavicular fracture (2). The experience of kinesio tape for clavicle fractures in daily practice implicates that it reduces pain and increases mobility, however there are no studies performed to approve these statements.

Kinesio tape is used for different (sport) injuries and some other conditions. The effects of kinesio tape are widespread, although the mechanism is not completely understood. The thought is that it improves lymphatic and blood circulation, reduces pain, realigns joints and reduces muscle tension.

Kinesio tape is used by physiotherapist for different shoulder issues. Saracoglu et al performed a systematic review about the effects of kinesio tape in addition to physiotherapy in cases of impingement syndrome (4). In this review three studies were included, which investigated the effectiveness of taping on pain and function in addition to physiotherapy. There was a positive effect on pain and function, but not all results were significant.

There are no studies performed about the effectiveness of kinesio tape in patients with clavicle fractures. The aim of our study is to investigate the effectiveness of kinesio tape in patients with clavicle fractures in comparison to the standard treatment (with sling). Our main outcome is the NRS-pain score.

Study objective

The aim of our study is to investigate the effectiveness of kinesio tape in patients with clavicle fractures in comparison to the standard treatment (with sling). Our main outcome is the NRS-pain score.

Primary Objective: Is there a difference in the decrease of NRS-score between patients treated with kinesio tape and a sling or a sling only?

Secondary Objective(s):

Is there a difference in the use of analgesics between both groups?

Is there a difference in the time to return to work, school or sport between both groups?

Is there a difference in the Constant score or DASH after six weeks?

Is there a difference in the number of patients with non-union after six weeks?

Study design

This is a randomized controlled trial. There are two treatment groups in this study. Patients treated only with a sling (group 1) and patients treated with a sling and kinesio tape (group 2). The duration of the study is 6 weeks for each patient.

Time schedule

T0: Patients are diagnosed with a clavicular fracture at the Emergency Department and will be approached for participation, when they meet the in- and exclusion criteria. Patients will be randomized in group 1 or 2 and fulfill a questionnaire (hand dominance, work, sport) after informed consent is obtained.

After randomization

Group 1 (treatment with sling)

T0: Patients will get a sling and instructions about the use of analgesics and the diary.

T0-1: Patients keep a diary about the NRS-score and the use of analgesics.

T1 (after 1 week): Patients have an appointment at the outpatient clinic to hand in the diary and get instructions about exercises for their shoulder.

T2-5 (after 2, 3, 4 and 5 weeks): Patients get an email or phone call about their NRS-score, use of analgesics and about return to work/school/sport

T6 (after 6 weeks): Patients have an appointment at the outpatient clinic for an X-ray and are asked to fulfill the DASH questionnaire and the constant score will be completed.

Group 2 (treatment with sling and kinesio tape)

T0: Patients will get a sling and kinesio tape. They get instructions about the use of analgesics and the diary.

T0-1: Patients keep a diary about the NRS-score and the use of analgesics.

T1 (after 1 week): Patients have an appointment at the outpatient clinic to hand in the diary and get instructions about exercises for their shoulder and replace the kinesio tape.

T2 (after 2 weeks): Patients return to the outpatient clinical for replacement of the kinesio tape and are asked about the NRS-score, use of analgesics and about the return to work/school/sport

T3 (after 3 weeks): Patients get an email or phone call about their NRS-score, use of analgesics and about the return to work/school/sport. They can remove the kinesio tape.

T4-5 (after 4 and 5 weeks): Patients get an email or phone call about their NRS-score, use of analgesics and about return to work/school/sport

T6 (after 6 weeks): Patients have an appointment at the outpatient clinic for an X-ray and are asked to fulfill a small questionnaire and the DASH questionnaire and the constant score will be completed.

Intervention

Patients in group 2 will be treated with kinesio tape.

The kinesio tape is a product of BSN Medical, which is called Leukotape K.

Study burden and risks

The risks for participants are very small. The only risk is irritation of the skin. The burdens of this study include one extra visit (group 2) and questionnaires for both groups. Those burdens are small and the aim of the study is to investigate another treatment method. This could improve the treatment of clavicle fractures in the future and hopefully would reduce the pain in patients with a clavicle fracture.

Contacts

Public

Isala Klinieken

Dokter van Heesweg 2
Zwolle 8025AB
NL

Scientific

Isala Klinieken

Dokter van Heesweg 2
Zwolle 8025AB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients > 18 years

Patients with a clavicular fracture

Trauma less than 24 hours ago

No other traumatic injury

Exclusion criteria

Pre-existent shoulder injuries (e.g. impingement, frozen shoulder)

Patients with cognitive problems

Patients with a language barrier

Patients with contra-indications for kinesio tape (allergic to acrylic adhesives)

Patients with an indication for surgery

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:	Recruiting
Start date (anticipated):	11-08-2020
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Kinesio tape
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date: 12-03-2020

Application type: First submission

Review commission: METC Isala Klinieken (Zwolle)

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	NL71385.075.19