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

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Goal of our study is to compare conservative treatment of mid-shaft clavicle fracture with Kinesio® clavicle tape combined with sling to conservative treatment with sling. Goal of our Pilot-studie is;Investorise if the VAS-score, the DASH…

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

Summary

ID

NL-OMON32528

Source
ToetsingOnline

Brief title
pilot-Conclaaf

Condition

- Fractures

Synonym
broken collarbone, mid-shaft clavicle fracture

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: clavicle fracture, conservative, Kinesio-tape, pilot study

Outcome measures

Primary outcome

Investorise if the VAS-score, the DASH questionairy and the Constant Shoulder Test are good for our greater studie. Given that this studie is a Pilotstudie with exploratory category we will look at this measurements. We will use the outcomes for instigate our head studie.

Secondary outcome

Investorise if the VAS-score, the DASH questionairy and the Constant Shoulder Test are good for our greater studie. Given that this studie is a Pilotstudie with exploratory category we will look at this measurements. We will use the outcomes for instigate our head studie

Study description

Background summary

Fractures of clavicula are frequently diagnosed. Of all fractures about 4 % are fractures of the clavicula. 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

Goal of our study is to compare conservative treatment of mid-shaft clavicle fracture with Kinesio® clavicle tape combined with sling to conservative treatment with sling.

Goal of our Pilot-studie is;
Investorise if the VAS-score, the DASH questionairy and the Constant Shoulder Test are sifficient enough for our greater RCT-studie about Kinesio® tape for clavicle fractures. Beside this we want to investicate how the placobo-tape works and if it is possible to hold it apart from de working tape, for the patient as well the doktor.

Study design

We will perform a prospective clinical pilot trial in our hospital *Onze Lieve Vrouwe Gasthuis* In this randomised, double-blind trial we compare an small experimental group (10 patients) and a small control group (10 patients) and a group without tape (10 patients). Inclusion- and exclusion criteria are formulated. 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. The third group gets only sling. This treatment is for 3 weeks. Tape will be exchanged every 5 days. After a period of 3 weeks only sling treatment continues, if requested by the patient. Outcome analysis for physical functioning and pain as our primary endpoints are measured by standard clinical follow-up and questionnaires: the Disabilities of the Arm, Shoulder and Hand (DASH) score, the Visual Analogue Scale (VAS) pain score, the Constant shoulder score. Furthermore, radiographs will be made at the useable times day 1 and day 10. After 1 month the pilot trial is finished. We also use a questionaire regarding the tape to analyze whether the placebotape will not have too much effect on the result of the research.

Furthermore treatment will be given compare the normal treatment of a claviculair fracture.

Beneath is schema from the dates and investications

Tijdstip van evaluatie VAS DASH RONTGEN Constant Shoulder Test
Day 1 X X X X
Day 10 X X X X

Day 20 X X X

Intervention

One group will receive the treatment with kinesio tape in addition to the sling, the other group will receive a tape without pressure and can be considered a fake tape. The last group don't get tape they only get a mitella.

Study burden and risks

Skin irritation could occor due to the use of tape.
The questions that need to be answered for the study will take about 10 to 15 minutes per visit. These inquiries are most of the time combined with regular visits.
The patients have to visit the Hospital 2 additional times to change the tape

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

Patients with a midclavicular fracture
In the age from 18 to 60 years
With a informed consent

Exclusion criteria

- Age less than eighteen or greater than sixty years
- Pathological fracture
- Open fracture
- Fracture older than 28 days after injury
- Mid-shaft clavicle fracture with >2 cm dislocation
- Fracture in the proximal or distal third of the clavicula
- Fracture with lesions of the neurological injury and skin perforation
- Patient with high probability of lost follow-up
- Trauma capitis or /and fracture at the upper extrimity simultaneous
- No mastery of dutch language
- 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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2009

Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	09-12-2008
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-03-2009
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	ID
CCMO	NL24061.100.08