Clinical study of comfort, pain and time to return to previous activities with conservative treatment of clavicle fractures with a 2 point-sling or broad arm sling

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ObjectivesThe aim of this study is to measure if there is a significant difference in comfort, pain and recovery of function between treatment with a broad arm sling or a 2 points-sling in patients with a collarbone fracture, treated conservatively....

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint injuries
Study type	Interventional

Summary

ID

NL-OMON52753

Source
ToetsingOnline

Brief title
COSTA study (Clavicula cOnservative Sling miTellA)

Condition

- Bone and joint injuries

Synonym
clavicle fracture, collar bone fracture

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: geen financiering

Intervention

Keyword: 2 point-sling, broad arm sling, comfort, pain, time to return to previous activities

Outcome measures

Primary outcome

Comfort of the immobilisation method is measured with the D-QUEST

Secondary outcome

Pain is measured with a visual analogue scale (VAS)

Recovery of function is measured with the DASH questionnaire

Study description

Background summary

Patients with a collarbone fracture who are treated conservatively at the Reinier de Graaf Gasthuis (RdGG) receive treatment with a broad arm sling, accordingly to the guidelines of trauma surgery (Trauma Regio West, 2016). This guideline gives two options for the standard conservative treatment; the broad arm sling and the 2 point-sling. As of now there is no literature available on the difference between these two immobilisation methods.
The aim of this study is to measure if there is a significant difference in comfort, pain and recovery of function between treatment with a broad arm sling or a 2 points-sling in patients with a collarbone fracture, treated conservatively.

Study objective

Objectives
The aim of this study is to measure if there is a significant difference in comfort, pain and recovery of function between treatment with a broad arm sling or a 2 points-sling in patients with a collarbone fracture, treated conservatively.

Hypothesis
Our hypothesis gives better comfort and thereby less pain and sooner recovery of function

Research question
Is there a significant difference between comfort, pain and recovery of function during recovering of a collar bone fracture at adolescents and adults with conservative treatment with a 2 points-sling or a broad arm sling?

Study design

A prospective stratified study at the Emergency Department of Reinier de Graaf Gasthuis, single centre study.

Intervention

One group will receive a broad arm sling (Merk: BSN Medical, REF: 72139-12, CE-nummer: 607662) the other group will receive a 2 point-sling (Merk: Klinion, REF: 132590, CE-nummer: 607662).

Study burden and risks

Patient who participate in the study have to fill in a questionnaire. One time at the ER visit and 3 times thereafter, at 1, 3, 6 weeks by mail or telephone. Filling in the questionnaire will take about five to ten minutes.
We expect that the treatment with a 2 point-sling will give more comfort and thereby possibly less pain and sooner recovery of function.
Patients enrolled in the study will not have additional risk.

Contacts

Public
Reinier de Graaf Groep

Reinier de Graafweg 3
Delft 2625AD
NL
Scientific
Reinier de Graaf Groep

Reinier de Graafweg 3
Delft 2625AD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age from 16 years
- Competent and adequate understanding of the Dutch language
- Conservative treatment of the fracture
- Acute fracture (<4 days old)
- Monotrauma
- Informed consent

Exclusion criteria

- Surgical treatment
- Fracture> 4 days old
- Pathological fracture
- Neuro-vascular abnormalities
- Multitrauma
- Familiar with shoulder complaints / condition with shoulders (eg rheumatism)
- Recurrent fracture
- Known pain syndrome or under treatment at outpatient pain clinic
- Epiphyse / metaphysis fracture

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:	Recruitment stopped
Start date (anticipated):	03-08-2020
Enrollment:	95
Type:	Actual

Medical products/devices used

Generic name:	2 point-sling
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	19-03-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	14-12-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	03-11-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) 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	NL70984.058.20