Treatment of subcpital fractures of the fifth metacarpal bone: functional treatment or splinting?

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The objective of this study is to investigate, in patients with closed subcapital fractures of the fifth metacarpal, whether functional treatment leads to better or equal results compared to splinting, regarding handfunction, fracture healing,...

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

Summary

ID

NL-OMON33707

Source
ToetsingOnline

Brief title
Functional treatment of subcapital fractures of the fifth metacarpal bone.

Condition

- Fractures

Synonym
boxer's fracture, handfracture

Research involving
Human

Sponsors and support

Primary sponsor: Rode Kruis Ziekenhuis
Source(s) of monetary or material Support: kosten worden door de aan het onderzoek participerende afdelingen (SEH en Chirurgie) van het RKZ gedragen

Intervention

Keyword: fifth metacarpal, fracture, functional treatment, immobilization

Outcome measures

Primary outcome

Clinical outcome, i.e. handfunction according to DASH-score

Secondary outcome

Fracture healing (including malunion/nonunion)

Range of motion of the fifth MCP joint, pulling strength of the fifth finger

Pain

Patient satisfaction

Time till resumption of daily activities and work

Study description

Background summary

Subcapital fractures of the fifth metacarpal are frequently seen in the ER. They account for 20 percent of all hand fractures. At present, the treatment of these fractures consists of splinting during three weeks. However, management of these fractures is still a matter of debate and an alternative treatment could be functional treatment, e.g. an elastic bandage, taping, a brace or a pressure bandage during one week.
Functional treatment offers several advantages in contrast to splinting. It costs less, is easier to apply, is patient-friendly and presumably leads to earlier recovery of handfunction and thus to earlier resumption of daily activities and return to work.
Preceding studies are of insufficient quality to make definitive conculsions (see protocol). Moreover, hand function has never been assessed in a validated manner. In this study, hand function will be assessed by means of the validated DASH-score, which has never been done before.

Study objective

The objective of this study is to investigate, in patients with closed

subcapital fractures of the fifth metacarpal, whether functional treatment leads to better or equal results compared to splinting, regarding handfunction, fracture healing, patient satisfaction, time till return to work and pain.

Study design

Between 01-01-2010 and 01-06-2010, adult patients (18 years or older with normal mental competence) who present at the Emergency Department of the Rode Kruis Hospital in Beverwijk with a subcapital fracture of the fifth metacarpal will be included in this study. All open fractures, fractures with a rotational deformity, fractures older than 72 hours, pathological fractures, re-fractures or fractures angulated by more than 70 degrees, will be excluded from the study. Before inclusion in the study, an informed consent will be obtained.
An anticipated number of 60 patients will be randomly allocated using block randomisation either to treatment with a volar plaster cast for a period of three weeks, or to treatment with an elastic bandage for one week. Follow up will be as usual, at 1, 3 and 6 weeks, and at 3 months. After 3 weeks and 3 months, an X-ray of the hand in two directions will be made, to evaluate fracture healing. Patients will be asked to fill in a DASH-questionnaire at presentation at the ER and at 6 weeks and 3 months follow up in order to evaluate handfunction. The results of these questionnaires will be compared to assess recovery of hand function. During the follow up visits, function of the fifth MCP joint (range of motion, grip strength) will be evaluated.
Any experienced pain will be evaluated by means of a VAS score list.

Intervention

One group will be receiving standard treatment, i.e. a volar plaster cast during 3 weeks (control group).
The other group will be treated with an elastic bandage during one week (intervention group).

Study burden and risks

Burden: one extra X-ray of the hand (+/- 0.2 mSv)
Although not anticipated, based on earlier studies, functional treatment may negatively influence fracture healing as compared to splinting. Also, it is possible that patients in the intervention group will expreience more pain.
The most important advantage of functional treatment is an anticipated earlier recovery of hand function and thus earlier resumption of daily activities and return to work.

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 from the age of 18 (male and female), with normal mental competence and a closed subcapital fracture of the fifth metacarpal presenting on the ER.

Exclusion criteria

open fractures
fractures with rotational deformity
fractures with an angulation by more than 70 degrees
age under 18 or incapacitated adults
pathological fractures
fractures older than 72 hours

re-fractures

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):	04-05-2010
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	Elastic bandage
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	20-11-2009
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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	NL24847.094.09