COnservative Treatment of MEtacarpal fractures with a Plasteraid Splint;(acronym COTMEPS)

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Primary objective:The primary objective of this observational study is evaluate the use of a plasteraid splint to gain and hold the desired 90-0-0 protective position in the conservative treatment of patients with metacarpal fractures of the second...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fractures
Study type	Observational non invasive

Summary

ID

NL-OMON32190

Source
ToetsingOnline

Brief title
COTMEPS

Condition

- Fractures

Synonym
hand fracture, metacarpal 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: conservative, fracture, metacarpal, plasteraid

Outcome measures

Primary outcome

Primary outcome is the DASH-DLV (Disabilities of the Arm, Shoulder and Hand-Dutch Language Version), a validated Dutch translation (Veehof 2002) of the original DASH (Beaton 2001) to evaluate disabilities and symptoms as a result of the metacarpal fracture treatment and to evaluate the ability of the Plasteraid splint to hold the desired 90-0-0 position. This DASH-DLV scoring form is filled out by the patients at t=0,1,4 and 8 weeks.

Secondary outcome

The following items will be secondary parameters/endpoints:

Full active range of motion (ROM) of the MCP joint 8 weeks following removal of the splint.

The need for physiotherapy and time to return to hobby or profession (at t=8 weeks) and loss to follow-up.

Study description

Background summary

The optimal conservative treatment of closed metacarpal fractures without severe rotation or ulnar / radial angulation remains subject of debate. Concerning the fifth metacarpal fracture no randomized controlled trial showed Level I evidence for the optimal type of conservative treatment (Poolman 2005). Fractures of the second to fourth metacarpal as well as the so called boxer's fracture (subcapital fracture of the fifth metacarpal) are traditionally immobilized with application of plaster-of-paris in the 'protective position', with the metacarpophalangeal joints flexed in 90 degrees while holding the

interphalangeal joints in (near-) extension. This position of 90-0-0 has long been considered as the golden standard in the conservative treatment of eligible metacarpal fractures.
Though several author's have reported good functional and anatomical results when metacarpal fractures were directly treated functional (Braakman 1998, Breddam 1995 , Konradsen 1990, Kuokkanen 1999, Statius Muller 2003), most centers still protocollary apply the 90-0-0 plaster-of-paris cast immobilization for a period of three to four weeks.

Most of the patients with metacarpal fractures initially present themselves at the emergency wards where decision is made according to local customs and protocols for an operative or conservative treatment strategy depending on factors as shortening of the bone, angulation (dorsovolar and ulnoradial), associated injury, rotation and wounds,.
If a conservative treatment is chosen, applying the plaster-of-paris cast in the desired protective position of 90-0-0 requires preferably a low-stress environment, patient cooperation and, most important, the experience of the personnel applying this specific plaster. Especially during night and weekends these factors are not infrequently suboptimal. Patients tend to cooperate badly during splinting as they might be intoxicated and acquired their fracture in a fight. The need for fracture reduction could further compromise the quality of the applied position of the plaster cast.

In most hospitals, patients with an aforementioned plaster-of-paris cast will have their follow-up one week after initial treatment. A radiological evaluation of the position of the fracture as well as the 'correctness' of the 90-0-0 position is reviewed in the outpatient clinic.
Inadequate positioning of the hand with plaster-of-paris remains an occurrence with potential consequences. First, there may be a need for reapplying the plaster by specialized personnel, which is time-consuming and should not be necessary. It puts a strain on both hospital resources (time) and patient (discomfort, pain). Second, the reapplication of the 90-0-0 plaster on an initially adequately reduced unstable metacarpal fracture might generate the secondary need for operative intervention. Third, if during the immobilization period a suboptimal fixed position of the hand with plaster-of-paris- for external reasons- is not corrected or seen by specialized personnel this might result in a longer period of revalidation, the need for physiotherapy and a prolonged inability to return to hobby or work with subsequent socio-economic consequences.

By immobilizing eligible metacarpal (including boxer's) fractures using a splint that has an anatomically preshaped position of 90-0-0 (a *plasteraid* splint) as alternative to current practice, the quality of the initial fixation might reduce short-term mentioned effects of initial suboptimal fixation.
We are not aware of any reported prospective trial treating metacarpal fractures with such a specific preshaped splint to gain the protective position, although good results with other supportive measures such as

compressive metacarpal gloves (McMahon 1994) or functional (metacarpal) braces around the wrist and hand (Hansen 1998, Harding 2001, Konradsen 1990, Sorensen 1993, Viegas 1987) have been reported. However, other studies reported skin necrosis due to pressure (Poolman 2005).
This pilot study will be conducted to evaluate the effectiveness of the plasterade splint as well as potential adverse effects. Depending on these initial study results a randomized trial will be performed to compare traditional treatment with using the plasteraid splint.

Study objective

Primary objective:
The primary objective of this observational study is evaluate the use of a plasteraid splint to gain and hold the desired 90-0-0 protective position in the conservative treatment of patients with metacarpal fractures of the second to fifth metacarpal. For this, functional results (measured using the DASH scoring form) will be registered. We want to evaluate the effectiveness and applicability of the plasteraid splint as well as potential adverse effects of the usage of such a splint.

Secondary objective:
The study is meant to lead to the development of the most optimal type of metacarpal splint.

Study design

The study will be an observational study, whereas 20 consecutive eligible patients (cumulative included in the five participating hospitals) with a traumatic metacarpal fracture of the second to fifth metacarpal will be treated using a plasteraid splint. The duration of the study will be twelve weeks.

Study burden and risks

The application of the splint is meant to gain and hold the position of protection as pursued with conventional casting. Therefore it is an instrument/tool to optimize the quality of current treatment. The use of a plasteraid splint might lead to adverse effects such as sub-splint transpiration and pressure sores if the splint size/shape is not optimal for the patients* anatomy treated

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 closed fractures of the metacarpal II-V (including boxer's fracture) that are not older than 72 hours, with or without the need for fracture reduction. Patients have to be older than 18 years old and without ipsilateral or associated injury (i.e. more fractures of the same hand).

Exclusion criteria

Open or pathological fractures, ipsilateral hand fractures, severe rotation deformity or ulnar/radial angulation, severe bone shortening, associated injury and the probability of loss to follow-up. A primary indication for operation according to local hospital customs and/or protocols is an exclusion criteria. Language barriers and/or intoxication which can*t guarantee adequate follow-up or understanding of the study and/or informed consent.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2008
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	plasteraid
Registration:	No

Ethics review

Approved WMO

Date:	06-05-2008
Application type:	First submission
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	NL21611.100.08