

Patient reported outcome in functional treatment (soft wrap and buddy taping) compared to casting in patients with uncomplicated subcapital metacarpal V fracture.

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Primary objective: Is functional treatment (soft wrap and buddy taping) superior in recovering hand function (QuickDASH) compared to casting in patients with uncomplicated subcapital MCV fracture? Secondary objectives: patient satisfaction, grip...

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

Summary

ID

NL-OMON50930

Source

ToetsingOnline

Brief title

Functional treatment of subcapital MCV fracture

Condition

- Fractures

Synonym

Boxer's fracture, Fracture metacarpal bone little finger

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

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

Intervention

Keyword: Casts, Compression Bandages, Metacarpal Bones, Patient Reported Outcome Measures, Surgical

Outcome measures

Primary outcome

Difference in QuickDASH score after 12 months

Secondary outcome

- How satisfied are patients with treatment with functional treatment or casting?
- What is the grip strength and ROM at 6 weeks and 6 months?
- What are the pain scores at week 0, 1, 3, 6 and month 6?
- How many days till return to work and sports?
- Which complications are seen and how often?

Could include: functional complaints (stiffness, reduced ROM) and secondary dislocation (x-rays only performed on clinical indication of attending physician).

- What is the influence of dominance of affected side on above?

Study description

Background summary

Uncomplicated subcapital fifth metacarpal (MCV) fractures are common injuries that are commonly treated with a cast. Functional treatment (buddy tape and/or

compression bandage) might result in quicker recovery of hand function, with similar outcomes on complications and pain scores. Functional treatment might benefit patients by quicker recovery, more comfort during treatment and less need for clinical follow-up appointments. Compared to existing literature, this study will have follow-up with clinical visits instead of only questionnaires. Furthermore, no reduction will be allowed to minimize differences in groups. Our intention is to achieve a greater sample size compared to existing literature to deliver reliable evidence for superiority of treatment with soft wrap and buddytape over casting.

Study objective

Primary objective: Is functional treatment (soft wrap and buddy taping) superior in recovering hand function (QuickDASH) compared to casting in patients with uncomplicated subcapital MCV fracture? Secondary objectives: patient satisfaction, grip strength and Range of Motion (ROM), pain scores, days till return to work/sports and occurrence of complications.

Study design

Multicenter randomized trial, non-blinded for patients and physicians.

Intervention

Intervention group will be treated with 1 week soft wrap (compression bandage) and buddytape of the 4th and 5th finger, followed by 2 weeks continued buddytape. Control group will be treated with 3 weeks of ulnar gutter cast (standard treatment).

Study burden and risks

Standard clinical visits at T=0, 1, 3 and 6 weeks. Additional clinical visit at month 6 and filling in QuickDASH/PROMIS at month 3. Every visit will include questionnaires (QuickDASH, PROMIS Upper Extremity v2.0 short form, Michigan Hand Questionnaire subscales pain and satisfaction) and at 2 visits physical examination of Range of Motion (ROM) and grip strength. The first visit questionnaire will include questions on patient characteristics (e.g. age, dominance, occupation).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

- Age >18 years old
- Isolated uncomplicated subcapital MCV fracture
- Understanding of Dutch or English language (written and spoken)
- Informed consent for participating

Exclusion criteria

- Age <18 years
- Bilateral fractures
- Indication for surgery (as decided by attending surgeon)
- Complicated fracture: Open, comminuted, intra-articular, rotation or angulation >70 degrees
- Other significant injuries (e.g. tendon or neurovascular injury, other fracture in same limb, polytrauma).

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:	Pending
Start date (anticipated):	01-11-2021
Enrollment:	116
Type:	Anticipated

Ethics review

Approved WMO	
Date:	04-06-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

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

CCMO

ID

NL75489.029.20