Outcome and cost-effectiveness of a dynamic Lucerne-cast versus a static forearm-cast in patients with fractures (shaft, intra-articular, sub-capital) of the metacarpal bone, requiring non-operative treatment

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Ninety percent of Metacarpal fractures (MCFs) (neck, shaft and intra-articular fractures) are treated non-operatively. Generally, non-operative treatment is defined as immobilization by a forearm cast. Recently it was shown that patients with 5th...

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

Summary

ID

NL-OMON48069

Source
ToetsingOnline

Brief title
CHAMPAGNE

Condition

- Other condition
- Fractures

Synonym
hand fracture, Metacarpal fracture

Health condition

Werkverzuim

Research involving
Human

Sponsors and support

Primary sponsor: Trauma chirurgie
Source(s) of monetary or material Support: ZonMw subsidie

Intervention

Keyword: Cost-analysis, Functional treatment, Lucerne-cast, Metacarpal fracture

Outcome measures

Primary outcome

Function, pain and disability expressed as change in Michigan Hand Questionnaire Score (MHQ) during the first three months. MHQ will be assessed at baseline/randomization, one week, three weeks, five weeks and twelve weeks after randomization. The MHQ is a validated tool for assessing functional outcome in patients with complaints of the hand. The MHQ is a questionnaire divided in six subscales; overall hand function, activities of daily living (ADLs), pain, work performance, aesthetics and patient satisfaction with hand function. Each subscale has a formula to calculate a score from 0 (severe disability) to 100 (no disability). The final score is a summation of the six individual item-scores divided by six and ranges from 0 (severe disability) to 100 (no disability).

Secondary outcome

- Michigan Hand Questionnaire Score measured at twelve months.

- Disability, expressed as change on Patient Specific Functional and pain Scales (PSFS) during the first three months. PFSF data will be gathered at baseline/randomization, one week, three weeks, five weeks and twelve weeks, six months and twelve months after randomization10. The PSFS is a list of 3-5 self-chosen activities, scored from 0 (difficult to perform activity) to 10 (no difficulty to perform activity). The final score goes from 0 (severe difficulty) tot 10 (no difficulty) and is a summation of the activity scores divided by the number of activities.
- Health literacy; the ability of an individual to access, understand, and use health-related information and services to make appropriate health decisions, with the Newest Vital Sign- Dutch langue version (NVS-D)11. The NVS-D is a 6-item questionnaire where a score of 4 or more right answers distinguish individuals with adequate versus inadequate health literacy. The NVS-D will be measured once, during an out-patient clinic appointment, preferably after randomization.
- Overall patient satisfaction (of the injury of the hand), on Visual Analogue Satisfaction Scale, scored from 0 (very dissatisfied) to 10 (completely satisfied), measured at at baseline/randomization, three weeks and twelve weeks, six months and twelve months after randomization
- Overall patient satisfaction (of the injury of the hand), on a 5 point scale from -2 (very dissatisfied) to +2 (completely satisfied) measured at baseline/randomization, three weeks and twelve weeks, six months and twelve months after randomization
- Patient satisfaction about improvement of function of the finger between the

operation and three months with the Visual Analogue Satisfaction Scale, scored from 0 (very dissatisfied) -to 10 (completely satisfied), measured at three months and patient satisfaction about improvement of function of the finger between three months and twelve months with the Visual Analogue Satisfaction Scale, scored from 0 (very dissatisfied) to 10 (completely satisfied), measured at twelve months.

- Patient satisfaction about improvement of function of the finger between operation and three months on a 5 point scale from -2 (no improvement) to +2 (completely improved), measured at three months, and patient satisfaction of improvement of function of the finger between three and twelve months on a 5 point scale from -2 (no improvement) to +2 (completely improved), measured at twelve months.
- Patient satisfaction about improvement of pain of the finger between operation and three months on a 5 point scale from -2 (no improvement) to +2 (completely improved), measured at three months and patient satisfaction of improvement of pain of the finger between three and twelve months on a 5 point scale from -2 (no improvement) to +2 (completely improved), measured at twelve months.
- Patient satisfaction on improvement of disability of the finger between operation and three months on a 5 point scale from -2 (no improvement) to- +2 (completely improved), measured at three months and patient satisfaction on improvement of disability of the finger between three and twelve months on a 5 point scale from -2 (no improvement) to +2 (completely improved), measured at twelve months.

- Patient satisfaction on aesthetics of the finger over the last three months on a 5 point scale from -2 (no improvement) to +2 (completely improved), measured at three months and patient satisfaction on aesthetics of the finger between three and twelve months on a 5 point scale from -2 (no improvement) to +2 (completely improved), measured at twelve months.
- Patient satisfaction on work performance over the last three months on a 5 point scale from -2 (no improvement) to +2 (completely improved), measured at three months and patient satisfaction on work performance between three and twelve months on a 5 point scale from -2 (no improvement) to +2 (completely improved), measured at twelve months.
- Overall satisfaction of the finger over the last 3 months on a 5 point scale from -2 (no improvement) to +2 (completely improved), measured at three months and overall satisfaction of the finger between three and twelve months on a 5 point scale from -2 (no improvement) to +2 (completely improved), measured at twelve months.
- Pain as indicated on a Visual Analogue Scale (VAS), where 0 implies no pain and 10 the worst possible pain, measured at baseline/randomization, three weeks and twelve weeks, six months and twelve months after randomization
- Patient-expectation; Pre-consultation expectation of the patient on recovery and post-consultation achievement of this expectation. At randomization patients will be asked what they expect to achieve in degree of improvement and restriction at a five-point scale; 1. No improvement, full restriction; 2. Slight improvement, serious restriction; 3. Moderate improvement, moderate restriction; 4. Substantial improvement, slight restriction; 5. Complete

improvement, no restriction.

At the last outpatient clinic visit (in general at twelve weeks after randomization) and at 12 months after randomization, patients will be asked to answer the same question with respect to their current health status. Achievement of expectation is expressed as the difference between their answer of the pre- and post-consultation questions.

- Total active motion (TAM) = Active Range Of Motion of the metacarpal-phalangeal joint, the proximal interphalangeal joint and the distal interphalangeal joint minus any extension deficits12. TAM is measured at randomization, three weeks and twelve weeks after randomization.

- Range of motion (ROM) of the wrist measured on both sides with a handheld goniometer. ROM includes pronation and supination, ulnar and radial deviation and palmar and dorsal flexion of the wrist. ROM is measured at randomization, three weeks and twelve weeks after randomization.

- Health care costs, productivity losses and out-of-pocket expenses with the adapted Dutch iMTA Medical Consumption Questionnaire and iMTA Productivity Cost Questionnaire (see economic evaluation below), measured at three weeks, twelve weeks and six and twelve months after randomization.

- Measurement of health status with the EQ-5D-5L at randomization/baseline, three weeks and twelve weeks and six and twelve months after randomization. This questionnaire consists of 5 items, measuring (at 5-point scales) whether patients experience problems, and if so, to what extent with regard to mobility, self-care, daily activities, pain/complaints, and mood.

- Health utility and quality adjusted life-years (see economic evaluation

below).

- Complications as; stiffness, re-operation, re-dislocation.

Study description

Background summary

The majority of metacarpal fractures (MCFs) (neck, shaft and intra-articular fractures) are treated nonoperatively. Generally, nonoperative MCFs are immobilized by a forearm cast, following the current guideline. (The thumb (MCF 1) is functionally more complex which requires tailor made treatment and therefore non comparable to MCF 2-5.) Plaster immobilization often results in stiffness and dysfunction of the metacarpal and proximal interphalangeal joints and wrist, often requiring hand therapy. Recently it was shown that patients with 5th neck MCFs had less stiffness and earlier return to work with concomitant lower costs when functionally treated. Due to these results, functional treatment of 5th neck MCF is recommended by the Dutch hand fracture guideline committee. Unfortunately, qualitatively focused studies describing functional treatment of MCFs 2-4 and 5th MCFs (other than neck fractures) are lacking. Therefore, we want to conduct a randomized study including these type of fractures. Functional outcome and cost-effectiveness will be studied comparing functional treatment by a Lucerne cast with immobilization by a forearm cast.

Study objective

Ninety percent of Metacarpal fractures (MCFs) (neck, shaft and intra-articular fractures) are treated non-operatively. Generally, non-operative treatment is defined as immobilization by a forearm cast. Recently it was shown that patients with 5th neck MCFs had less stiffness and earlier return to work with concomitant lower costs when functionally treated. Qualitatively focused studies describing functional treatment of MCFs 2-4 and 5th MCFs (other than neck fractures) are lacking. Therefore, to demonstrate that functional treatment is also superior in these types of metacarpal fractures, our objective is to compare the functional outcome and cost-effectiveness of a functional Lucerne cast with immobilization by a conventional forearm cast in adult patients.

Study design

Multicentre randomized clinical superiority trial. Study inclusion period 1.5 years.

Intervention

-USUAL/STANDARD CARE
The Dutch hand fracture guideline committee recommends to immobilize patients for 3-5 weeks in a forearm cast resulting in stiffness of wrist and fingers after cast removal. Standard treatment by forearm cast consists of:
1. Immobilization by a forearm cast constructed at the emergency department(ED)
2. Replacement of this ED-cast by a plastic, customized forearm cast within 1 week at the cast-room.
3. Removal of this plastic cast after 3 weeks (4 weeks after trauma)

-INTERVENTION
Functional treatment of wrist and fingers by a Lucerne cast. Functional treatment will lead to less stiffness. The principle of the Lucerne cast is securing the MCP joints in intrinsic position but allowing movement of the proximal interphalangeal joints and the wrist joint. Standard functional treatment by a Lucerne cast consists of:
1. Immobilization by a forearm cast constructed at the ED
2. Replacement of this ED-cast by a plastic, customized Lucerne cast within 1 week at the cast-room.
3. Removal of this Lucerne cast after 3 weeks (4 weeks after trauma).

Study burden and risks

Both treatment modalities are standard care. The treatment of choice is currently based on surgeon*s preference. Out-patient clinic visits are at one and four weeks and at three months. All visits are standard care in case of conservative treatment of a metacarpal fracture (if the emergency department visit occurs during evening or night shifts and the patient is randomized in the intervention group, the patient needs to return to the cast room for a custom made Lucerne cast the next day). During the visits patients will be asked if there are any complaints and/or complications. Physical examination like assessment of the range of motion of the hand and wrist will be executed. Additional to standard care, questionnaires are received at one, two, four, six weeks and at three, six and twelve months. Questionnaires can be filled out at home at all times, no additional out-patient clinic visits are necessary for the questionnaires. Patients are asked to fill out MHQ, PSFS, EQ-5D-5L,the Visual Analogue Pain Scale, Visual Analogue Satisfaction scale and 5-point satisfaction scores. Additionally, a questionnaire on any use of health care, health related expenses and absence from work will be administered and patients will be asked to fill out the NVS-D once. Subjects could experience mild discomfort during physical examination and testing, but this will be no different than physical examination during routine follow-up. The burden experienced regarding time spent on questionnaires is difficult to estimate but will most likely not exceed two and a half hours in the total follow-up

duration of this study (1 year).

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

a. Population (base)
- Adult patients with metacarpal fractures (MCFs) 2-4 and 5th MCFs (other than neck fractures), requiring nonoperative treatment. The fracture needs to be diagnosed on a radiograph at the emergency department.b. Inclusion criteria
- Patients >=18 years
- Single MCF 2-4 (neck, shaft or intra-articular)and 5th MCFs (other than neck fractures)

Exclusion criteria

- Operation indication; functional restrictions due to shortening, rotation or angulation
- Volar angulation of the 5th ray >= 30
- Volar angulation of the 4th ray >=30
- Volar angulation of the 3th and 2nd ray >=20
- Rotation disorders; clinical functional restriction such as scissoring fingers
- Metacarpal shortening by segmental bone loss or < 50% bone to bone contact
- Irreducible dislocations
- Operative treatment
- Fifth metacarpal neck fractures
- Multiple metacarpal fractures in one hand
- Metacarpal fracture of the first ray
- Operative treatment
- Absence of one of the following radiographs: Posterior-Anterior, 3/4-shot.
- Patients with impaired hand function prior to injury due to arthrosis/neurological disorders of the upper limb
- Multiple trauma patients (Injury Severity Score (ISS) >=16)
- Other injuries in the ipsilateral extremity
- Insufficient comprehension of the Dutch language to understand a rehabilitation program and other treatment information as judged by the attending physician
- Patient suffering from disorders of bone metabolism other than osteoporosis (i.e. Paget*s disease, renal osteodystrophy, osteomalacia)
- Patients suffering from connective tissue disease or (joint) hyper-flexibility disorders such as Marfan*s, Ehler Danlos or other related disorders

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-05-2020
Enrollment:	106
Type:	Actual

Ethics review

Approved WMO

Date:	07-01-2020
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

ID: 20452
Source: NTR
Title:

In other registers

Register	ID
Other	Nederlands trial register
CCMO	NL67401.100.19