Outcome and cost-effectiveness of a dynamic Lucerne-cast versus immobilization by forearm-cast in patients with FraCtures (neck, sHaft, intra-Articular) of the MetacarPAl bone, requirinG Non-operative trEatment.

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Functional treatment with a Lucerne cast leads to less stiffness, better functional outcome, earlier return to work and concomitant lower costs compared to immobilization with a forearm cast in patients with metacarpal fractures 2-4 and 5th MCFs (...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20452

Bron
NTR

Verkorte titel
CHAMPAGNE-Study

Aandoening

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.

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: -

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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 hand6,9. 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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

Functional treatment with a Lucerne cast leads to less stiffness, better functional outcome, earlier return to work and concomitant lower costs compared to immobilization with a forearm cast in patients with metacarpal fractures 2-4 and 5th MCFs (other than neck fractures).

Onderzoeksopzet

1: Preparation (1-2)
2: Inclusion (3-20)
3: Follow-up (21-32)

4: Data analysis/ Publishing (33-36)

Onderzoeksproduct en/of interventie

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 flexion 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 emergency department (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).

USUAL/STANDARD CARE
The Dutch hand fracture guideline committee recommended to immobilize patients for 3-5 weeks resulting in stiffness after cast removal. Standard treatment by forearm cast consists of:
1. Immobilization by a forearm cast constructed at the 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)

Contactpersonen

Publiek

OLVG/Maasstad ziekenhuis
Dorien Salentijn

0633744440

Wetenschappelijk

OLVG/Maasstad ziekenhuis
Dorien Salentijn

0633744440

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients ≥18 years
- Single MCF 2-4 (neck, shaft or intra-articular)and 5th MCFs (other than neck fractures)
- Conservative treatment with a dynamic or forearm cast for four weeks.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2019
Aantal proefpersonen:	106
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48069
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7712
CCMO	NL67401.100.19
OMON	NL-OMON48069

Resultaten