Cast OFF-2: One week of plaster cast immobilization for non-reduced distal radius fractures. An implementation study.

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The objective of this study is to successfully implement one week of plaster cast immobilization for non-reduced distal radius fractures in twelve centers and to evaluate functional outcome, acceptability and cost-effectiveness.

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

Samenvatting

ID

NL-OMON26972

Bron
NTR

Verkorte titel
Cast OFF-2

Aandoening

Distal radius fractures

Ondersteuning

Primaire sponsor: International Grant form the Orthopaedic Trauma Association.
Overige ondersteuning: OTA international Grant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameter is the acceptability of the study (number of protocol violations).

Toelichting onderzoek

Achtergrond van het onderzoek

Distal radius fracture is a common fracture and the majority of these fractures is stable. Of all diagnosed fractures 17% is a distal radius fracture of which a large part is extra-articular and one third is non-displaced. Due to the large variation in advisement's for treatment for non-reduced distal radius fracture, the usual practice is often four to five weeks of immobilization for non-reduced distal radius fractures. Existing evidence for one-week immobilization shows that one week of immobilization is safe and does not lead to more secondary displacement. Additionally, shorter immobilization periods for non-reduced distal radius fractures may also be cost-effective. Shorter immobilization periods may lead to less outpatient clinic visits, less home care for elderly people and may lead to earlier return to work and other social activities.
In this study, we aim to successfully implement one week of plaster cast immobilization for non-reduced distal radius fractures in twelve centers and to evaluate the functional outcome and cost-effectiveness.
The study will be performed using a multicenter stepped wedge design. Patients with an isolated non-reduced distal radius fracture between the age of 18 and 85 years old will be included in the study.
All hospitals will start with their usual treatment (Condition A), often plaster cast immobilization for three to five weeks. When the cluster/hospital is randomized to switch treatment, all patients (including patients who are excluded for this study) will be treated following condition B. Patients in condition B, will have an immobilization period of one week with plaster cast.
The primary outcome of this study will be the acceptability of the study. In addition, functional outcome, return to activity, cost-effectiveness and complications will be measured. Patients will be seen at the outpatient clinic after one week and four to five weeks post injury. The follow-up via questionnaires will take place after six weeks and three- six- and twelve months.

Doel van het onderzoek

The objective of this study is to successfully implement one week of plaster cast immobilization for non-reduced distal radius fractures in twelve centers and to evaluate functional outcome, acceptability and cost-effectiveness.

Onderzoeksopzet

The outpatient clinic follow-up will take place after one week and four-five weeks.
After four weeks post injury patients will be followed via questionnaires sent after six weeks, three- six- and twelve months.

Onderzoeksproduct en/of interventie

The study will be performed using a stepped wedge design. All hospitals will start with their usual treatment (Condition A), often plaster cast immobilization for three to five weeks. When the cluster/hospital is randomized to switch treatment, all patients (including patients who are excluded for this study) will be treated following condition B. Patients in the condition B will have an immobilization period of one week of plaster cast. Patients will get a splint or cast at the emergency department. After one week, an appointment is scheduled at the outpatient clinic. Instead of a plaster cast change, the splint or cast will be removed and physical examination will be performed. After removal of plaster cast, information is given about the importance of using their arm and doing the exercises of the home exercise program.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• age between 18 and 85 years
• isolated acute distal radius fracture; intra and extra articular
• closed reduction is not performed
• non-operative treatment with cast immobilisation
• ability to perform Activities of Daily Living independently
• ability to give informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• multiple injured patient
• reduction is indicated/performed
• operative treatment
• no understanding of Dutch language
• a patient with extra care at home; in need of a caregiver or professional for Activities of Daily Living
• open fractures
• history of surgically treated wrist fracture on the currently injured side
• estimated high risk of secondary displacement by surgeon due to comorbidities, high risk of falling or life circumstances

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2021
Aantal proefpersonen:	440
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

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9278
Ander register	CMO Nijmegen-Arnhem : CMO 2021-7308

Resultaten