Displaced distal radial fractures in adult patients: Four weeks versus Six weeks of cast immobilization after reduction, a randomized controlled trial.

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Nowadays, many dislocated fractures of the distal radius will be treated operatively. However, a significant amount of dislocated distal radial fractures do not need operative treatment and will be treated by reduction and immobilization. Usually an...

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

Summary

ID

NL-OMON46494

Source
ToetsingOnline

Brief title
DR PIP II - Distal Radius Plaster Immobilization Period II

Condition

- Fractures
- Bone and joint therapeutic procedures

Synonym
distal radial fracture, forearm fracture, wrist fracture

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: Distal radial fracture, immobilization, reduction, Wrist fracture

Outcome measures

Primary outcome

The primary outcome measure is the PRWE (Patient Related Wrist Evaluation) score after one year.

PRWE score is the most responsive instrument for evaluating the outcome in patients with distal radius fractures. The PRWE is a validated 15-item (scored 1-10), self-reported questionnaire designed to help describe the disability experienced by people with disorders of the wrist and also to monitor changes in symptoms and function over time. Scores will be transformed to a 0-100 score. A higher score indicates greater disability.

Secondary outcome

1. The QuickDASH (Disabilities of the Arm, Shoulder and Hand) and SF-36 score after one year;16

2. Functional outcome after 8 weeks, 3 months and 6 months ;

3. Range of motion;

4. Pain level after 8 weeks, 3 months, 6 months and 1 year;

5. Lidström-score;

6. Fracture related complications: Number of secondary dislocations after cast

removal; Number of re-interventions;Delayed-/nonunion; CRPS.

Subjective functional outcome will be measured by QuickDash and PRWE. Range of motion will be measured using a goniometer. Pain level will be measured by a pain dairy [Appendix VI] and determined using a 10-point Visual Analog Scale (VAS), in which zero implies no pain and ten implies the worst possible pain. Radiological outcome and the amount of dislocation will be assessed by an independent radiologist by use of the Lidström-score [Appendix VII]. Delayed- or nonunion will be defined as an delay of arrest in fracture healing after 3 or 6 months, respectively.

In addition to the outcome variables mentioned above, the following data will be collected: Intrinsic variables (baseline data): Age, gender, hand dominance, body weight, smoking, occupation, hobbies, sporting activities.

Study description

Background summary

Up to 30% of patients with a dislocated distal radius fracture suffer from long-term functional restrictions following conservative treatment. It remains unclear, whether duration of cast immobilisation influences functional outcome.

Study objective

Nowadays, many dislocated fractures of the distal radius will be treated operatively. However, a significant amount of dislocated distal radial fractures do not need operative treatment and will be treated by reduction and immobilization. Usually an immobilization period of five or six weeks is preferred as non-operative treatment of reduced distal radial fractures. Despite the minimal evidence in literature this immobilization period can be questioned. A randomized clinical trial with sufficient power is needed to provide scientific support for a preferred treatment strategy for reduced distal radial fractures. The aim of this trial is to compare the results of four weeks of cast immobilization with six weeks of cast immobilization of

reduced distal radial fractures with respect to functional outcome, the incidence of non-union, pain scores and complications.

Study design

This study will be conducted as a multi-center prospective randomized clinical trial in two large size teaching hospitals . In this study four weeks of plaster immobilization is compared with six weeks of plaster immobilization. Patients will be treated in a lower arm cast. Post cast treatment will be the same for both groups, in which additional physiotherapy is advised and exercises to train wrist function will be given [Appendix I]. The study will start immediately after approval of METC.

Intervention

patients will be randomized in two study groups: six weeks (control group), or four weeks (intervention group)

Study burden and risks

Both periods of immobilization are generally accepted ways of treatment. up to 30% of patients with a dislocated distal radius fracture suffer from long-term functional restrictions following conservative treatment. The duration of immobilization of distal radius fractures depends on whether these fractures can be considered stable fractures, besides type of fracture and age of the patient most distal radial fractures are liable to displace within the first two weeks, only 7% to 8% displace after this time, and none after six weeks. The chance of secondary dislocation after removal of the cast after four weeks seems to be negligible.

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

1. Age > 18 years;
2. Primary displaced unilateral fracture of the distal radius;
3. Independent for activities of daily living.

Exclusion criteria

1. Fracture of contralateral wrist;
2. Ipsilateral fractures proximal of the DRF;
3. Pre-existent abnormalities or functional deficits of the fractured wrist;
4. Open fractures.
5. Language ability to understand the Dutch patient information and questionnaires.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-07-2019
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	29-08-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-01-2019
Application type:	Amendment
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	ID
CCMO	NL62861.029.17

Study results

Date completed:	01-02-2022
Actual enrolment:	100