Cast-OFF trial: One versus four-five weeks cast immobilization for non reduced distal radius fractures. A randomized clinical trial. A feasibility study.

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The aim of this feasibility study is to define whether one week of plaster cast treatment is possible and can lead to better functional results, with at least the same patient satisfaction and complications. This feasibility study will be used to...

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

Summary

ID

NL-OMON45589

Source
ToetsingOnline

Brief title
Cast-OFF trial

Condition

- Fractures

Synonym
distal radius fracture; wrist fracture

Research involving
Human

Sponsors and support

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

Intervention

Keyword: distal radius fracture, early mobilisation, functional outcome, non-operative treatment

Outcome measures

Primary outcome

The main study parameter in this study will be the patient reported outcome (PRO) measured with the patient reported wrist evaluation (PRWE) questionnaire.

Secondary outcome

1. In addition to the PRWE, we will use the DASH questionnaire for upper extremity functioning. The two questionnaires will be measured after six weeks and three, six and twelve months. Comprehensive PRO measures will also be measured. This a more generic instrument that captures aspects of health status and quality of life beyond hand functioning. The Short Form * 36 (SF-36) will be used to measure this.

2. Complications. The complication checklist for DRF from McKay will be used for scoring the complications after a DRF. The clinical record, questions by interview and questionnaires will be used to complete the checklist. The Budapest diagnostic criteria will be used to score CRPS, a complication which can occur after a DRF. In addition, pain and post traumatic pain will be scored. The visual analogue scale (VAS) will be asked and the PROMIS pain interference questionnaire will be used for pain interference and diagnosing

post traumatic pain.

3. Process evaluation. The evaluation will be focused on:

- Willingness of participants. Every patient who can be included in the study will be analyzed. Patients who did not want to be included are asked what their reasons are.

- Acceptability of the study. Participants will be asked to give feedback on study design and give their reaction to the intervention. This will be asked at 12 months* follow-up.

- Process evaluation. The study design will be evaluated afterwards. This includes, evaluation of inclusion process, the intervention and follow-up with questionnaires (response rates, adherence/compliance rates, etc) [Arain, 2010].

Study description

Background summary

Distal radius fracture (DRF) is a common fracture of which the incidence appears to be increasing worldwide. On average, a total of 17% of all diagnosed fractures are DRF*s.
In the Dutch guideline for DRF the treatment advice for DRF, without reduction, is treatment with plaster cast or brace for one-three weeks. Despite the advice in the guideline and despite several studies from the 90*s showing that plaster cast treatment of a stable DRF for one week is safe, the usual length of plaster cast treatment for stable DRF is four-six weeks. In addition, recent studies have also shown that a long period of immobilization can lead to more post traumatic pain by increasing disuse and kinesiophobia.
This evidence suggests that the usual duration (4-6 weeks) of plaster cast treatment for DRF is unnecessary.

Study objective

The aim of this feasibility study is to define whether one week of plaster cast

treatment is possible and can lead to better functional results, with at least the same patient satisfaction and complications. This feasibility study will be used to define the sample size of the future RCT.

Study design

The present study is an open multi centre randomized clinical feasibility trial for treatment of a DRF with one week versus four-five weeks of plaster cast.

Intervention

Patients will be included at emergency room. After one week they will be randomized for the intervention or control group. The patients in the intervention group follow the same protocol as the conventional group but instead of four-five weeks of plaster cast the patients will be treated for one week with a plaster cast. After another three-four weeks, patients will be seen by the casting nurse for a quick control.

Study burden and risks

For patients in this study the burden to participate is minimal. Patients need to fill in the different questionnaires and if necessary are called by the investigator for further explanation. No extra visits to the hospital are necessary.
In addition, the risk for the patient is negligible. A shorter immobilization has been proved to be safe. Displacement of the fracture is minor and gives no significant difference with longer plaster cast treatment. However, studies also show that patients who were treated without plaster cast showed more pain in the first week. This is the reason why we give patients plaster cast for 1 week and reduce the risk of having pain. The benefit is that patients will mobilize the wrist faster, functional result will be better, work can be done quicker and a shorter period of plaster cast will be given which leads to less complications caused by long immobilization.

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

Age between 18 and 75 years.
Isolated acute distal radius fracture
Closed reduction is not performed
Non-operative treatment with cast immobilisation
Understanding of Dutch language

Exclusion criteria

under the age of 18 or older than 75 years
multiple injured patient
reduction is indicated/performed
operative treatment
cognitive disorder

Study design

Design

Study type: Interventional

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-01-2020
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	26-07-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL59217.091.17

Study results

Date completed:	31-01-2020
Actual enrolment:	40