Non- or minimally displaced distal radius fractures in adult patients <50 years of age: Three weeks of cast immobilisation versus one week of brace immobilisation, a Multicenter Randomised Controlled Trial.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Interventional

Summary

ID

NL-OMON56114

Source
ToetsingOnline

Brief title
DR PIP Study - Distal Radius Plaster Immobilisation Period Study

Condition

- Bone disorders (excl congenital and fractures)
- Bone and joint therapeutic procedures

Synonym
distal radius fracture, forearm fracture, Wrist Fracture

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cast/brace immobilisation, Distal radius fractures, non operative treatment

Outcome measures

Primary outcome

patient-reported outcome after six months measured by PRWE (Patient Related Wrist Evaluation) score.

The PRWE is a validated 15-item (scored 1-10) self-reported questionnaire and is the best questionnaire for evaluating the patient reported outcome in case of DRFs. Patients rate their outcome on a 0-10 scale on pain and functional outcome, and scores will be transformed to a 0-100 score. A higher score indicates greater disability.

Secondary outcome

1. The qDASH (Quick Disabilities of the Arm, Shoulder and Hand) score after 6 weeks, and 6 months

2. PRWE after 6 weeks

3. Range of motion after 6 weeks, and 6 months

4. Pain (VAS-score) at arrival at ED, after cast/brace is applied, in the first week after brace/cast removal, 6 weeks, and 6 months

5. Radiological outcome at 6 weeks, and 6 months

6. Complications

7. Cost-effectiveness (measured by EQ-5D, iMCQ and iPCQ questionnaires)

The DASH Outcome Measure is a validated 30-item self-reported questionnaire for patients with disorders of the arm, shoulder and hand. The QuickDASH (qDASH) is the shortened version of the DASH Outcome Measure, using 11 items instead of 30 (scored 1-5) to measure pain and functional outcome. At least 10 of the 11 items must be completed to calculate a score. The scores will be transformed to a 0-100. A higher score indicates greater disability.

The range of motion will be measured by using a goniometer: volar/dorsal flexion, radial/ulnar deviation, and pronation/supination, will be determined. The pain will be measured by using the VAS-score. VAS-score is a widely used method for pain assessments. Patients score their pain on a scale of 1-10. A higher score indicated a higher level of pain. The VAS-score will be measured on the ED at arrival and after application of the brace of cast. Patients will also receive a dairy after cast removal to record their pain score.

Radiological outcome will be measured; dorsal and volar tilt in degrees, radial height in millimetres and ulnar variance in millimetres will be calculated directly after trauma, and after six weeks and six months.

Complications contain secondary displacement (radial shortening >3mm, dorsal tilt >10° or intra-articular step-off >2mm), delayed/non-union, re-interventions, complex regional pain syndrome (CRPS), tendon injuries (ruptures and tendinitis), nerve injuries (carpal tunnel syndrome and lesions),

and distal radial ulnar joint disability.

Cost-effectiveness and cost-utility of non- or minimally displaced DRFs treated by three weeks of cast immobilisation or one week of brace immobilisation will be analysed. The perspective of this study is societal, and therefore both direct and indirect costs due to the DRF will be considered. Direct costs will include treatment, follow up visits at the outpatient clinic, additional visits to health care professionals, and the treatment of complications. Non-health care related costs include expenses to travel to and from the hospital. Indirect costs are based on absenteeism of work, or loss of working hours due to cast-immobilisation or pain. To estimate health care costs, the Friction-Cost method will be used to analyse the loss of production for an individual worker. This analysis is based on a cost effectiveness analysis of a study on the non-operative versus the operative treatment of DRFs. To analyse cost-effectiveness and cost-utility, the EuoQuol 5D (EQ-5D), Productivity Cost Questionnaire (iPCQ) and the Medical Consumption questionnaires (iMCQ) will be used.

Study description

Background summary

Currently, non- or minimally displaced distal radius fractures are treated by three to five weeks of cast immobilisation. Many patients with a distal radius fracture suffer from long-term functional restrictions, which might be related to stiffness due to cast immobilisation.

Study objective

Current literature indicates that one week of cast or brace immobilisation is

safe, however, no level one evidence is available. This trial aims to compare one week of brace immobilisation with three weeks of cast immobilisation in non- or minimally displaced distal radius fractures. We hypothesize that one week of brace immobilisation is non-inferior to three or more weeks of cast immobilisation.

Study design

This study will be conducted as a multicenter-prospective randomized clinical trial in three hospitals. In this study three weeks of cat immobilization is compared to one week of brace immobilization. Patients will be treated in a lower arm cast or a prefab brace. Post-immobilization treatment will be equal for both groups. The study will start at the 1th of January 2023.

Intervention

Intervention group: one week of brace immobilization
control group: three weeks of cast immobilization (general care)

Study burden and risks

Both treatment options are generally accepted ways of treatment.
Up to 30% of the patients with a distal radius fracture suffer form long-term functional restrictions following cast immobilization. As non or minimally displaced fracture are considered stable fractures, they did not displace during the trauma, so they will not displace later on, the risk of secondary displacement in these fractures is negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. 18-50 years (to eliminate osteoporosis);
2. Primary non- or minimally gedisplaced DRF;
3. Independent for activities of daily living.

Exclusion criteria

1. Fracture of the contralateral wrist;
2. Ipsilateral fractures, proximal of the DRF;
3. Pre-existent abnormalities or functional deficits of the fractured wrist;
4. Open fractures;
5. Poly trauma patiënten
6. 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:	Pending
Start date (anticipated):	01-01-2024
Enrollment:	74
Type:	Anticipated

Ethics review

Approved WMO

Date:	18-10-2023
Application type:	First submission
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	NL81638.029.22