Distal Radius Plaster Immobilization Period II; A randomized trial comparing four weeks of plaster cast immobilization with six weeks of plaster cast immobilization in adult patients with reduced distal radius fractures.

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Ethical review	Not approved
Status	Will not start
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON37378

Source
ToetsingOnline

Brief title
DR PIP II

Condition

- Joint disorders

Synonym
distal radial fracture, wrist fracture

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Dislocated Distal radius, immobilization

Outcome measures

Primary outcome

Functional outcome in adult patients with a distal radius fracture as assessed

using the

a. Quick Disability of Arm, Shoulder and Hand (DASH) score and

b. Patient Related Wrist Evaluation

Secondary outcome

Secondary Objective(s):

1. Range of motion

2. Pain (assessed by the VAS scale)

3. Time to union

4. Complications: complex regional pain syndrome and mal/ nonunion

Study description

Background summary

The incidence of distal radial fractures is 400/100.000 in the Netherlands. Therefore, these fractures represent a large amount of the daily workload for practicing orthopedic and trauma surgeons. Most patients with distal radius fractures can be treated non-operatively in a plaster of Paris, with excellent functional results.

In case of conservative treatment of reduced distal radius fractures a little is known about the duration of plaster cast immobilization. Usually a period of six weeks is chosen. Christensen showed in a clinical controlled trial with 33 patient that immobilization of nearly of non-dislocated distal radius fractures could be reduced from 5 till 3 weeks. Vang Hansen confirmed these findings later with a prospective comparative with 100 patients. Jensen showed in a randomized trial with 62 patients that even one week of immobilization was sufficient.
In the above mentioned studies it has already been shown that a reduction in period of immobilization could be possible. However the above mentioned studies have their limitations in follow up and their modest group of patients. moreover these studies do not represent the reduced distal radial fractures.

Study objective

The aim of the study is to prove that the functional outcome of distal radial fractures is better after four weeks of plaster cast immobilization than after six weeks of plaster cast immobilization in adult patients.

Study design

This study will be conducted as a prospective randomized controlled clinical trial in which four weeks of plaster cast immobilization is compared to six weeks of plaster cast immobilization. Patients with distal radius fractures will be initially managed on the emergency department. Using the criteria for misalignment (dorsal angulation >15°, volar tilt >20°, radial inclination >15° and, ulnar variance >5mm) the patients will be included if closed reduction is necessary.
Patients will be asked informed consent after fulfilling the above-mentioned inclusion and exclusion criteria. Two (non-treating) trauma surgeons as external referees will also determine the degree of misalignment and the AO classification blinded from the scoring by the treating physician. Thereafter patients will be randomized into a group in which the plaster cast immobilization is continued for four weeks or six weeks.

Intervention

One group will have four weeks of plaster immbilization and the other group will have six weeks of plaster immobilization

Study burden and risks

Literature indicates that both treatment options are accepted for distal radial fractures. No clear advantage for one treatment option is found at present in the literature, although there is no level I evidence present. Both treatment options have their known complications: stiffness of the joint and pain due to

malunion.
The expectation of this study is that four weeks of plaster immobilization is beneficial for the patient with a distal radius fracture. This risk of specific complications is low and generally similar in both treatment options. Moreover, the burden of the study is not much higher compared to standard treatment.

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. Unilateral fracture of distal radius with misalignment (dorsal angulation >15°, volar tilt >20°, radial inclination >15° and, ulnar variance >5mm)
3. Independent for activities of daily living

Exclusion criteria

1. Fracture of contralateral arm
2. Other fractures at the ipsilateral arm (excluded carpal fractures)
3. Pre-existent abnormalities fractured distal radius
4. Open fractures
5. Inadequate reduction of distal radius at 1 week follow-up at the outpatient department

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	66
Type:	Anticipated

Ethics review

Not approved

Date:	28-09-2012
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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	NL38463.094.11