Distal Radius Plaster Immobilization Period I; A randomized trial comparing three weeks of plaster cast immobilization versus five weeks of plaster cast immobilization in adult patients with distal radius fractures.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON41417

Source
ToetsingOnline

Brief title
DR PIP I

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: Distal radius, immobilization length

Outcome measures

Primary outcome

Primary Objective:

Does three weeks of plaster cast immobilization when compared to five weeks of plaster cast immobilization lead to an improved or equal 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.

Distal radial fractures are usually treated on an outpatient basis . In the last 100 years, most distal radial fractures in adults have been treated conservatively. Over the last decade, concurrent with the introduction of locking plates, open reduction and internal fixation of distal radial fractures has become more popular. The choice of treatment methods is also influenced by the patient's general medical condition, the expected functional loading (activity demands), and patient motivation.

In case of conservative treatment of distal radius fractures a little is known about the duration of plaster cast immobilization. Usually a period of 4 till five 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.

Study objective

The aim of the study is to compare the functional outcome of distal radial fractures after three weeks of plaster cast immobilization with five weeks of plaster cast immobilization. We think that a shorter immobilization period of distal radial fractures lead to a better finctional outcome.

Study design

This study will be conducted as a prospective randomized controlled clinical trial in which three weeks of plaster cast immobilization is compared to five 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 not 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 three weeks or five weeks.

Intervention

One group will have three weeks of plaster immbilization and the other group will have five weeks of plaster immobilization

Study burden and risks

Literature indicates that both treatment options from the study are accepted for distal radius fractures. No clear advantage for one treatment options 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 three 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 without misalignment
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

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:	Recruiting
Start date (anticipated):	01-09-2012
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	31-07-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-02-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-11-2015
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	NL38449.094.11