Internal Plate Fixation versus Plaster in Complete Articular Distal Radius Fractures

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To determine the difference in functional outcome between open reduction and internal platefixation and closed reduction and plaster immobilisation in patients with displaced complete articular distal radius fractures.

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

Summary

ID

NL-OMON45181

Source
ToetsingOnline

Brief title
VIPAR

Condition

- Fractures

Synonym
dislocated articular distal radius fracture, wrist fracture

Research involving
Human

Sponsors and support

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

Intervention

Keyword: articular, fracture, ORIF, plaster

Outcome measures

Primary outcome

Patient-Rated Wrist Evaluation score (PRWE)

Secondary outcome

Disability of Arm, Shoulder and Hand score (DASH)

Quality of life (SF-36)

Pain as indicated on a Visual Analogue Scale (VAS)

Range of Motion (ROM)

Grip strength (measured with a grip strength meter)

Radiological outcome of the wristjoint

Complications

Costs and absence from work

Study description

Background summary

The ideal treatment for patients with displaced complete articular distal radius fractures remains a controversial issue. Loss of reduction of a acceptable reduced fracture is not uncommon. Recently published literature shows good to excellent results in both patients treated with closed reduction and plaster immobilization and in patients treated with open reposition and internal fixation (ORIF) with a plate. However, these studies do not differentiate between displaced intra- and extra-articular fractures. Recently, the use of volar locking plates has become more popular, due to its better performance in osteoporotic bone. Moreover, these plates can be perfectly combined with dorsal and radial column plates. The anatomic reduction and stable fixation of these fractures allows for early mobilization and may

theoretically lead to a better function.

Study objective

To determine the difference in functional outcome between open reduction and internal platefixation and closed reduction and plaster immobilisation in patients with displaced complete articular distal radius fractures.

Study design

(multicentre) Randomized Controlled Trial

Intervention

This study will randomise between open reduction and internal platefixation and closed reduction and plaster immobilisation.

Study burden and risks

The treatment that patients will receive is a component of the standard treatment of care, which currently merely depends on the surgeon*s preference, and the complexity of the fracture and the current National Guidelines for distal radius fractures. Patients will be asked to return to the hospital for follow-up at one, two/three and five/six weeks, three months, six months and at twelve months. All visits are part of standard care following a fracture treated in this hospital. During these visits patients will be asked about any complaints and/or complications and physical examination will be performed. The assessment of the range of motion of the wrist will take approximately five minutes. Additional to standard care, patients will be asked to fill out four questionnaires at six weeks, three months, six months and one year. Patients will be asked to rate their pain on a Visual Analogue Scale and give an estimation of the type and quantity of pain medication taken during all visits. They will also be asked to fill out the PRWE, DASH score and the SF-36 form. This will take approximately thirty minutes of their time. Additionally, a questionnaire on any expenses and absence from work will be administered. This will take another ten minutes. Patients can fill out these four questionnaires at home online on our website, or in the waiting room before the actual consult takes place. Subjects could experience mild discomfort during physical examination and testing, but this will be no different from physical examination during routine follow-up. X-rays will be taken during every visit of which only the final radiographs at one year are additional to standard care. The burden experienced regarding time spent is difficult to estimate but will most likely not exceed 40 minutes. In the total duration of this study, patients will spend an approximate 190 minutes extra.

The risks are comparable to those that the standard treatment involves. This

comprises the standard risk for undergoing a surgical procedure, including risks related to anesthesia, neurovascular damage and post-operative wound infection. The risks of closed reduction and plaster immobilization include stiffness, redislocation, malunion, loss of function and complex regional pain syndrome. Close follow-up and a protocol of treatment, identical to the standard one, will be applied in every subject. Reduction of risks will be done according to inclusion and exclusion criteria. If complications arise, the treating physician will proportionate the adequate treatment according to the current protocols of treatment based on the published literature.

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

Patients from 18 up to and including 75 years with a displaced complete articular distal

radius fracture (AO type C)

Exclusion criteria

* Patients with impaired wrist function prior to injury due to arthrosis/neurological disorders of the upper limb
* Open distal radius fractures
* Multiple trauma patients (Injury Severity Score (ISS) *16)
* Other fractures of the affected extremity (except ulnar styloid process)
* Fracture of other wrist
* Insufficient comprehension of the Dutch language to understand a rehabilitation program and other treatment information as judged by the attending physician
* Patient suffering from disorders of bone metabolism other than osteoporosis (i.e. Paget*s disease, renal osteodystrophy, osteomalacia)
* Patients suffering from connective tissue disease or (joint) hyperflexibility disorders such as Marfan*s, Ehler Danlos or other related disorders

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:	Recruitment stopped
Start date (anticipated):	19-06-2015
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	20-01-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-01-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-04-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-04-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-05-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-07-2015

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-09-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-11-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-11-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-01-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-03-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-03-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-07-2016

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-03-2017
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

ID: 29516
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL51544.018.14
OMON	NL-OMON29516