Volar Internal Plate Fixation versus Plaster in Extra-articular distal Radial fractures (VIPER)

Published: 24-09-2012
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To compare the functional outcome of ORIF with a volar locking plate to closed reduction and plaster immobilisation in patients with dislocated extra-articular distal radius fractures.

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

Summary

ID

NL-OMON41583

Source
ToetsingOnline

Brief title
VIPER

Condition

- Fractures

Synonym
displaced distal radius fracture, fractures wrist

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: AMC Graduate School Scholarship

Intervention

Keyword: fracture, ORIF, plaster, treatment

Outcome measures

Primary outcome

Disability Arm Shoulder Hand Score (DASH)

Secondary outcome

Patient-Rated Wrist Evaluation score (PRWE), quality of life (QoL SF-36), pain

as indicated on a Visual Analogue Scale (VAS), Range of Motion (ROM),

radiological outcome and complications, costs and absence from work.

Study description

Background summary

The ideal treatment for patients with dislocated extra-articular distal radius fractures remains a controversial issue. Excellent results have been described both in patients treated with a plaster and in patients treated with open reposition and internal fixation (ORIF) with a volar locking plate. Recently, the use of Volar Locking Plates has become more popular, due to its better performance in osteoporotic bone. Moreover, anatomic reduction and stable fixation of these fractures allows for early mobilization and may theoretically lead to a better function.

Study objective

To compare the functional outcome of ORIF with a volar locking plate to closed reduction and plaster immobilisation in patients with dislocated extra-articular distal radius fractures.

Study design

Randomized Controlled Trial

Intervention

This study will randomise between open reduction and internal fixation with a volar locking plate and plaster immobilisation.

Study burden and risks

The treatment that patients will receive is a component of the standard treatment of care which currently depends on the surgeon*s preference and the complexity of the fracture. Patients will be asked to return to the hospital for follow up at one, three and 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 fill out a DASH form, rate their pain on a Visual Analogue Scale and give an estimation of the type and quantity of pain medication taken during all visits. This will take approximately ten minutes of their time. The two other questionnaires: the PRWE score and the SF-36 will approximately take another ten minutes each. Additionally, a questionnaire on any expenses and absence from work will me administered. This will take another twenty minutes. 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 30 minutes. In the total duration of this study, patients will spend an approximate 230 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 plaster immobilization include 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 published literature.

Patients who are treated with volar plate fixation are expected to achieve better results regarding mobility and recovery of wrist function.

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

diagnosed with a dislocated extra-articular distal radius fracture

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
· Other fractures in the affected extremity
· 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:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-10-2012
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	24-09-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-12-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-12-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	01-02-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-03-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-03-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-01-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-03-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-03-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-04-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	18-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-09-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-12-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-01-2015
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:	15-09-2015
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

ID: 26639
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL37754.018.12
OMON	NL-OMON26639