VIPER, operatie versus gips bij polsfracturen.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26639

Source
Nationaal Trial Register

Brief title
VIPER

Health condition

Distal radius fractures

Sponsors and support

Primary sponsor: Academic Medical Centre Amsterdam
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

Disability of the Arm, Shoulder and Hand (DASH) questionnaire

Secondary outcome

Patient-Rated Wrist Evaluation (PRWE) score, quality of life (SF-36), pain as indicated on a

Visual Analogue Scale (VAS), range of motion (ROM), grip strength, radiological outcome and complications.

Study description

Background summary

Rationale:

The ideal treatment for 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.

Objective:

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

Study design:

Multi Center Randomized Controlled Trial.

Study population:

All consecutive adult patients with an AO type A distal radius fracture which was successfully reduced within 12 hrs of presentation at Emergency department of the participating hospitals.

Intervention:

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

Main study parameters/endpoints:

Primary outcome: Disability of the Arm, Shoulder and Hand (DASH) score. Seconday 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.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Patients will be asked to return to the hospital for follow up at; one, three and six weeks and three, six and twelve months. During these visits patients will be asked about any complaints and/or complications and physical examination will be performed. The risks associated with the treatment under study comprise standard risk for undergoing a surgical procedure related to anaesthesia, post-operative pain and wound infection.

Study objective

Anatomic reduction and stable fixation of distal radius fractures by volar plating allows for early mobilization and therefore leads to a better function.

Study design

1 week, 2 weeks, 6 weeks, 3 months, 6 months, 1 year.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients >18 years <75;

2. AO type A displaced distal radius fracture;

3. Fracture displacement is defined by the AO foundation as fragments not perfectly anatomically aligned;

4. Acceptable closed reduction obtained immediately after presentation at the Emergency Department (<12hrs).

Exclusion criteria

1. Patients with impaired wrist function prior to injury due to arthrosis/neurological disorders of the upper limb;

2. Open distal radius fractures;

3. Multiple trauma patients;

4. Other fractures in the affected extremity;

5. Insufficient comprehension of the Dutch language to understand a rehabilitation program and other treatment information as judged by the attending physician;

6. Patient suffering from disorders of bone metabolism other than osteoporosis (i.e. Paget’s disease, renal osteodystrophy, osteomalacia);

7. 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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2012
Enrollment:	90
Type:	Actual

Ethics review

Positive opinion

Date:	22-10-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41583
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2966
NTR-old	NTR3113
CCMO	NL37754.018.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Register	ID
OMON	NL-OMON41583

Study results

Summary results
N/A