Operation or Plaster in Wrist Fractures

No registrations found.

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

Summary

ID

NL-OMON29516

Source
Nationaal Trial Register

Brief title
VIPAR

Health condition

dislocated, articular, distal radius, fracture, ORIF, plaster
gedisloceerd, articulair, distale radius, fractuur, ORIF, gips

Sponsors and support

Primary sponsor: Academic Medical Center, Amsterdam
Source(s) of monetary or material Support: Self-financing

Intervention

Outcome measures

Primary outcome

PRWE

Secondary outcome

DASH, SF36, VAS, ROM, grip strength, radiographic outcomes, cost-effectiveness and cost-utility

Study description

Background summary

There is no consensus about the best treatment for patients with displaced complete articular distal radius fractures (AO type C fractures). Despite this lack of consensus and the lack of available literature on comparative data to guide treatment for this patient population, operative treatment with plate fixation has gained popularity. The aim of our study is to compare the functional outcome of open reduction and plate fixation with closed reduction and plaster immobilisation in adult patients (18-65 years) with displaced complete articular distal radius fractures.

Study objective

Open reduction and internal plate fixation has a better functional outcome compared to closed reduction and plaster immobilisation.

Study design

1 week, 2/3 weeks, 6 weeks, 3 monhts, 6 months, 12 months

Intervention

Open reduction and internal plate fixation versus plaster immobilisation

Contacts

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Eligibility criteria

Inclusion criteria

• Patients from 18 – 75 years

• AO type C displaced distal radius fracture, as classified on lateral, posterior anterior and lateral carporadial radiographs/CT-scan by a radiologist or trauma surgeon

• Fracture displacement is defined by the AO foundation as ‘fragments not perfectly anatomically aligned’. Acceptable closed reduction obtained immediately after admission to the Emergency Department (<12hrs)

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 from 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

Recruitment

NL

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

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	03-12-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45181
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4777
NTR-old	NTR4915
CCMO	NL51544.018.14
OMON	NL-OMON45181

Study results