

Wrist fractures treated with plaster cast or operation: what leads to the best outcome in patients older than 50 years?

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29311

Source

Nationaal Trial Register

Brief title

RADIUS STUDY: Randomized Assessment of Distal radius fracture Interventions in Unstable Subtypes

Health condition

distal radius
fracture
plate fixation
plaster cast immobilization

Sponsors and support

Primary sponsor: None

Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Main study parameter/endpoint

Functional outcome parameters:

Disability of Arm, Shoulder and Hand (DASH) score, Musculoskeletal Function Assessment (MFA)

Secondary outcome

Secondary study parameters/endpoints

Functional outcome parameters:

Short Form 36 (SF-36) health survey questionnaire, Patient Related Wrist Evaluation (PRWE), Range of motion, Pain level (VAS), Cost-effectiveness analysis

Radiographic analysis: Lidstrom score

Complications:

complex regional pain syndrome type-I, infection, re-operation, arthrodesis, general surgical complications (pneumonia, myocardial infarction, etc).

Study description

Background summary

Complication rate for treatment of displaced intra-articular distal radius fractures is low, although functional disability remains a significant problem with up to 30% of patients suffering long-term functional restrictions after conservative treatment. Whether operative correction improves this functional outcome compared to conservative treatment remains unclear.

Study objective

Open reduction and internal fixation (ORIF) using locking-plate distal radius osteosynthesis leads to an improved functional outcome (DASH score) in elderly (>50 years) (independent in activities of daily living) patients with a displaced distal radius fracture (AO type A2, A3, B1, C1, and C2).

Study design

Follow-up 1 month, and 3, 6, 12 and 24 months

Intervention

Open reduction and internal fixation using locking-plate and angular stable screw fixation versus plaster cast immobilization

Contacts

Public

Department of Surgery
University Medical Center Maastricht
PO Box 5800
M. Poeze
Maastricht 6202 AZ
The Netherlands
+31 (0)43 3876543

Scientific

Department of Surgery
University Medical Center Maastricht
PO Box 5800
M. Poeze
Maastricht 6202 AZ
The Netherlands
+31 (0)43 3876543

Eligibility criteria

Inclusion criteria

1. Age > 50 years
2. Primary displaced unilateral fracture of distal radius (open fractures are included)
 - a. AO (Arbeitsgemeinschaft für Osteosynthesefragen) type A2
 - b. AO type A3
 - c. AO type B1
 - d. AO type C1
 - e. AO type C2

3. Independent for activities of daily living (yes/no question)
4. Inadequate reduction of distal radius fracture at emergency department (For specific criteria see below) and/or
5. Inadequate reduction of distal radius at 1 week follow-up at the outpatient department: Therapeutic failure is defined as fracture displacement when the dorsal or volar angulations are more than 10°, intra-articular step-off > 1mm, or the ulnar variance is more than 3mm. This failure accounts for both redisplacement after initial adequate alignment during conservative treatment (including manipulative reduction) on the emergency department and for secondary failure after surgical reduction.

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. Primary unilateral fracture distal radius AO type A1, B2, B3 and C3
5. Pathological fractures (due to metastasis, secondary osteoporosis)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-06-2008
Enrollment:	200

Type: Anticipated

Ethics review

Not applicable

Application type: Not applicable

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
NTR-new	NL1235
NTR-old	NTR1280
Other	MEC azM : 08-2-009
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A