

Gips vergeleken met opereren voor een gebroken pols, wat geeft een beter resultaat bij ouderen?

No registrations found.

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

Summary

ID

NL-OMON24458

Source

NTR

Brief title

DART

Health condition

Distal radius fracture elderly

Sponsors and support

Primary sponsor: Dirk ter Meulen, d.p.termeylen@olvg.nl, OLVG oost

Source(s) of monetary or material Support: ZonMw doelmatigheidsonderzoek SEENEZ project

Intervention

Outcome measures

Primary outcome

- Wrist function as reported by the patient (Patient-Rated Wrist Evaluation score) (PRWE)) 1 year after trauma

Secondary outcome

- Wrist function as reported by the patient (Disabilities of the Arm, Shoulder and Hand (DASH))
- Quality of life as reported by the patient (EQ-5D)
- Patient reported pain catastrophizing (Pain Catastrophizing Scale (PCS))
- Costs evaluation questionnaire
- ROM (range of motion)

Study description

Background summary

Rationale: there is no consensus about the optimal treatment of displaced intra-articular distal radius fractures in elderly patients. To ensure optimal functional outcome there is a tendency to operate. However, there is no evidence that supports the surgical treatment of patients aged 65 years or older and in the absence of clinical trials it stays unclear how elderly patients with intra-articular fractures should be treated.

Objective: to compare the functional outcome after open reduction and internal fixation with non-operative cast treatment for elderly patients with displaced intra-articular distal radius fractures.

Study design: multi-center randomized controlled trial with a non-inferiority design. Economic evaluation alongside a randomized controlled multi-center trial.

Study population: all consecutive patients aged between 65 years and older with displaced intra-articular (AO Type C) distal radius fractures, with a not acceptable reduction within 3 weeks following trauma.

Intervention: patients will be randomized between open reduction and internal fixation (intervention group) and plaster immobilization (control group).

Study objective

Cast treatment is not inferior to surgical open reduction and internal fixation in terms of patient related outcome measurements.

Study design

T1: 1 week

T2: 3 weeks

T3: 6 weeks

T4: 3 months

T5: 6 months

T6: 9 months

T7: 12 months

Intervention

Surgery: open reduction internal fixation by volar (and possibly dorsal plating).

Conservative: cast treatment

Contacts

Public

OLVG oost

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Scientific

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Eligibility criteria

Inclusion criteria

- >65 years at time of trauma
- Intra-articular distal radius fracture (AO type C*)
- One or more of the following fracture characteristics within 3 weeks post-trauma (including secondary dislocation):

$\leq 15^\circ$ inclination

<5 mm radial length

>15° dorsal tilt

>20° volar tilt

intra-articular gap or step-off >2 mm

- < 3 weeks post trauma
- Living independent at home (e.g. not in a retirement home)
- Fit for surgery
- Mentally competent

The patient must be able to fully understand the consequences of participation. This includes that the patient must be aware of the burden that the research project provides, the possible complications in both treatment arms and the possibility to not participate in the trial. Furthermore he or she must be able to fill out the questionnaires.

- Dutch fluency and literacy
- Informed consent

Exclusion criteria

- Open fractures
- Neurovascular damage

- Multiple-trauma patients (ISS >16)
- Other fractures in the injured extremity other than ulnar styloid process fractures
- Contralateral fracture of the forearm

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-02-2017
Enrollment:	154
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	NL6201
NTR-old	NTR6365
Other	NL56858.100.16 : NCT03009890

Study results

Summary results

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