How should we treat a patient with a distal radius fracture after closed reduction? A cluster RCT*

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To evaluate the cost-effectiveness of treatment with a circumferential cast compared to treatment with a splint, in patients with a reduced distal radius fracture. The hypothesis is that reduced distal radius fractures treated with a circumferential...

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

Summary

ID

NL-OMON48181

Source
ToetsingOnline

Brief title
CAST study

Condition

- Fractures

Synonym
distal radius fracture, fracture of forearm bone

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMw doelmatigheid

Intervention

Keyword: cast, cost-effectiveness, Distal radius fracture, splint

Outcome measures

Primary outcome

Difference between groups in proportion of fracture re-displacement of the initial reduced distal radius fracture. Besides, differences in medical consumption, absence from work or decreased productivity, and patient costs, will be assessed.

Secondary outcome

- pain medication use

- surgical interventions

- physical examination of range of motion of the arm and grip strength

- recovery of functioning: QUICK-DASH and PRWE questionnaires

- change in pain severity: number rating scale (NRS) for pain

- general quality of life: EQ-5D-5L

- total costs: intramural and extramural medical costs (iMCQ) and productivity loss (iPCQ)

- adverse events.

Study description

Background summary

Distal radius fractures (DRF) are the most common fractures in the adult population. There is no consensus on conservative treatment of a displaced DRF.

Study objective

To evaluate the cost-effectiveness of treatment with a circumferential cast compared to treatment with a splint, in patients with a reduced distal radius fracture.
The hypothesis is that reduced distal radius fractures treated with a circumferential cast instead of a splint, results in less fracture re-displacement, fewer surgical interventions, less complications and lower costs

Study design

Cluster randomized design, randomization will take place on hospital level. All patients will be followed for 1 year.

Intervention

In one group the fracture will be initially immobilized with circumferential below-elbow cast, and in the other group the fracture will be initially immobilized with below-elbow splint.

Study burden and risks

The burden is primarily time (visit of outpatient clinic, and to fill in questionnaires). There is no direct benefit from participation or group relatedness.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria: 18 year or older, with a primary displaced fracture of the distal radius which is treated conservatively after closed reduction, and who are willing to comply with the study protocol.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: failure to reach proper fracture alignment (5) after reduction(s) in the emergency room, inability to complete study forms due to any mental status or insufficient command of the Dutch language, both-bone forearm fracture (styloid ulnae fracture excluded), concomitant injuries to ipsilateral extremity or multi-traumata.

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):	29-05-2020
Enrollment:	610
Type:	Actual

Ethics review

Approved WMO Date:	30-10-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-12-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-02-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-04-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-05-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-08-2021

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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: 27921
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL71020.078.19