

Should a patient with a suspected scaphoid fracture be treated with cast? An RCT

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To evaluate the cost-effectiveness of a supportive bandage compared to cast for patients with a clinically suspected scaphoid fracture with normal initial radiographs. Our hypothesis is that patients with a clinically suspected scaphoid fracture...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON50288

Source

ToetsingOnline

Brief title

Treatment of suspected scaphoid fracture

Condition

- Fractures

Synonym

fracture of bone of the wrist, suspected scaphoid fracture

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: "suspected scaphoid fracture", bandage, cast, cost-effectiveness

Outcome measures

Primary outcome

Difference between groups in change between baseline and 3 months follow-up in functional outcome.

Secondary outcome

Besides, differences in medical consumption, pain medication use, adverse events, absence from work or decreased productivity, and patient costs, will be assessed.

Study description

Background summary

The usual care is that patients with clinical complaints of the wrist suspected for a fracture of scaphoid, without radiographic signs of a fracture, will be treated with cast. Although all suspected scaphoid fractures are immobilized in cast, only ten percent of patients appears to have a true scaphoid fracture during follow-up. Therefore 90% of patients are unnecessary immobilized in cast. A bandage seems to be a good alternative.

Study objective

To evaluate the cost-effectiveness of a supportive bandage compared to cast for patients with a clinically suspected scaphoid fracture with normal initial radiographs.

Our hypothesis is that patients with a clinically suspected scaphoid fracture with normal initial radiographs treated with a bandage, have minimally equal functional outcome after 3 months compared to cast, but with lower costs.

Study design

Open-labeled multicenter RCT (non-inferiority). Comparison of

cost-effectiveness of supportive bandage versus cast as treatment for patients with a clinically suspected scaphoid fracture with normal initial radiographs.

Intervention

INTERVENTION

Supportive bandage for 3 days, and patients are allowed to move the wrist driven by the amount of pain.

USUAL CARE /COMPARISON

Below-elbow cast for 2 weeks.

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: patients aged 18 year or older, with clinically suspected scaphoid fracture without radiological sign of a fracture, injury less than 48 hours ago, and 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: concomitant injuries to the ipsilateral extremity and inability to complete study forms due to any mental status or insufficient command of the Dutch or English language.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	12-06-2018
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO

Date: 22-12-2017

Application type: First submission

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

Approved WMO

Date: 20-04-2018

Application type: Amendment

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

Approved WMO

Date: 13-08-2018

Application type: Amendment

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

Approved WMO

Date: 11-12-2018

Application type: Amendment

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

Approved WMO

Date: 03-01-2019

Application type: Amendment

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

Approved WMO

Date: 17-07-2019

Application type: Amendment

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

Approved WMO

Date: 13-02-2020

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: 20183

Source: NTR

Title:

In other registers

Register	ID
CCMO	NL62620.078.17
OMON	NL-OMON20183