# Non-displaced scaphoid fractures: a clinical trial of cast immobilization including vs. excluding the thumb

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Fractures |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON33925

**Source**
ToetsingOnline

**Brief title**
Scaphoid Casting Trial

### Condition

- Fractures

**Synonym**
fracture of a carpal bone in the wrist, Scaphoid fracture

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W,Onderzoeker GA Buijze heeft een persoonlijke Toptalent-beurs van NWO;alhoewel niet direct toekomend aan

het onderzoek.

## Intervention

**Keyword:** Cast, Fracture, Scaphoid, Thumb

## Outcome measures

### Primary outcome

Union, defined as fracture consolidation as determined on CT-scan.

### Secondary outcome

Wrist function and pain, determined by validated outcome scores.

# Study description

### Background summary

Scaphoid fractures occur in young active patients and have become notorious for their potential for nonunion. Non-displaced fractures of the waist (midportion) of the scaphoid can be treated successfully in a cast. The relationship between the extent of immobilization and the elimination of non-union has still to be demonstrated. Clay et al found comparable results when comparing thumb immobilization with a cast that allows the thumb to move freely. Our standard care for nondisplaced fractures of the scaphoid is to offer the patient cast immobilization where a below elbow cast including the thumb is applied for 10 weeks.

Plain radiographs are the most common method of assessment of fracture union but their lack of reliability is notorious . In particular the study of Dias and colleagues which showed poor agreement among eight observers and an unacceptably low degree of reproducibility when analyzing the inter-observer agreement and reproducibility of radiographs for the determination of union at twelve weeks. They concluded that the final outcome of radiographic union should be based on appearances after a minimal follow-up of 6 months and probably a year.

### Study objective

The primary goal of this study is to determine the union as determined on both radiographically and computed tomography. This will allow us to compare these two modalities for the determination of union 10 weeks and six months after

fracture*our hypothesis based upon existing literature is that CT scan will be a more reliable predictor of eventual radiographic union 6 months after injury.

As a secondary goal of this study, we will compare the two different configurations of below-elbow cast in the treatment for non-displaced fractures of the waist of the scaphoid: one including the thumb (so-called thumb spica cast) and one not including the thumb (a standard below-elbow or short arm cast). We will use the DASH questionnaire to measure health status at six months and compare the outcome in these two groups.

### Study design

The subjects will complete a data sheet with demographic information at the initial visit. The nondisplaced scafoid fracture needs to be confirmed on CT-scan. After obtaining informed consent, the patients will be randomly assigned by computer to either short arm casting with thumb immobilization (Group 1) or short arm casting without thumb immobilization (Group 2). At ten weeks (visit 1), an x-ray and a CT scan will be obtained. At final follow up at six months (visit 2), subjects will have an x-ray. If the fracture appears to be healing on x-rays, no further imaging studies (CT scan) will be done. In addition, Range of motion and grip strength will be measured. Subjects will be asked to fill out a DASH questionnaire. Also, ordinal scale for pain, Mayo wrist score and Gartland /Werely score will be obtained on physical examination.

### Intervention

Patients will be randomly assigned by computer to either short arm casting with thumb immobilization (Group 1) or short arm casting without thumb immobilization (Group 2).

### Study burden and risks

We do not anticipate treatment related risks related to participation in this study, but it is possible (though unlikely) that one casting method will prove inferior to the other with respect to healing of the fracture. It is standard in many parts of the world not to include the thumb in a cast. Studies addressing the difference in outcome between the two cast variations show comparable results.

## Contacts

### Public

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

1. Adult patient (age 18 years or greater)
2. Isolated fracture of the scaphoid in the injured upper extremity
3. No displacement of the scaphoid fracture on CT scan with axial (0,5mm), sagital (1,0mm) and coronal (1,0mm) reconstructions.

## Exclusion criteria

1. Any associated ipsilateral ligament injury or fracture in the injured extremity
2. Pregnant patient

# Study design

### Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |
| Primary purpose: | Diagnostic |

### Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-05-2009 |
| Enrollment: | 60 |
| Type: | Anticipated |

### Medical products/devices used

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|---|---|
| Generic name: | Cast |
| Registration: | No |

## Ethics review

Approved WMO

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| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

## 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 |
| --- | --- |
| CCMO | NL26188.018.09 |