

Long term follow-up of fractures and bone bruises of the scaphoid

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To determine if bone bruise of the scaphoid can develop arthritis or non-union when untreated. And to evaluate if a fracture can cause long term complications when adequately treated.

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

Summary

ID

NL-OMON37578

Source

ToetsingOnline

Brief title

Scaphoid FU

Condition

- Fractures

Synonym

bone bruising, Scaphoid fractures

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: arthritis, Follow-up, Fracture, Scaphoid

Outcome measures

Primary outcome

Functional and radiological outcome of the wrist after scaphoid fracture (treated with a cast) or bone bruise.

Secondary outcome

- Patient satisfaction (NRS)
- operations
- Range of Motion

Study description

Background summary

A fracture of the scaphoid is known for its severe long term complications when non-union occurs. This information is not known for adequately treated fractures. In addition, recent literature showed that bone bruising on MRI can progress into development of a true fracture. The difference between a bone bruise and a true fracture is difficult to distinguish, while bone bruise is usually not treated with a cast. The clinical consequences of bone bruising are unknown.

Study objective

To determine if bone bruise of the scaphoid can develop arthritis or non-union when untreated. And to evaluate if a fracture can cause long term complications when adequately treated.

Study design

long term follow-up retrospective cohort.

Study burden and risks

- 1 visit to the outpatient clinic of 30 minutes
- 2 x 4 radiographs of the injured and healthy wrist (0,001 mSv)
- 3 questionnaires (DASH, PRWE, SF-36)

Contacts

Public

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

18 years of age or older
scaphoid fracture at least 1 year ago
bone bruise at least 1 year ago

Exclusion criteria

Patients younger than 16 years of age at time of injury
ipsilateral wrist fractures
rheumatoid arthritis
cognitive dysfunction limiting clinical evaluation

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-07-2012

Enrollment: 200

Type: Actual

Ethics review

Approved WMO

Date: 13-03-2012

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	NL39506.018.12