

Cost effectiveness of a fast MRI in occult scaphoid fractures.

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We want to find out whether the new protocol (with a fast MRI) is more cost-effective than the current protocol (consisting of 10 days cast). Primary Objective: To find out whether the new MRI protocol is more cost-effective than the old protocol....

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

Summary

ID

NL-OMON43690

Source

ToetsingOnline

Brief title

Fast MRI in scaphoid fractures

Condition

- Fractures

Synonym

fracture of the scaphoid bone, scaphoid fracture

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

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

Intervention

Keyword: cost effectiveness, fracture, MRI, scaphoid

Outcome measures

Primary outcome

Costs of treatment, including days not attending work, days of plaster treatment, times of outpatient clinic visits, number of x-rays, times of consulting the casting-technician, costs of MRI.

Secondary outcome

Hand functioning after 6 weeks, measured by two questionnaires, the Patient Rated Wrist and Hand Evaluation and the QuickDash.

Both questionnaires are available in Dutch and have been validated. Time for completion: 10 minutes.

Study description

Background summary

At the UMCG, 300 patients per year attend the CSO with a suspected fracture of the scaphoid bone (the scaphoid is a carpal bone). However, the specificity and sensitivity of physical examination is low. Thereby, sometimes (15-20%) the fracture is not seen on the initial x-ray (thesis Beeres, 2008). Therefore, when there is suspicion of a scaphoid fracture, patients are treated with a cast and are seen at the outpatient clinic after 10 days again. Patients are treated with a cast even when there is a minimum suspicion, since leaving a scaphoid fracture untreated can have serious adverse consequences (necrosis and pseudarthrosis).

If patients are still in pain after ten days, a photograph is repeated.

Sometimes a fracture is seen then, the sensitivity of the second X-ray is however low. If patients have no pain, they are discharged from follow-up, and are thought to have no fracture. This appears to be the case in approximately 85% of patients.

So, the vast majority (85%) of patients is treated unnecessary with a cast for 10 days.

MRI has a negative predictive value of 99% concerning the presence of a scaphoid fracture (Yin, 2010). So, if it is possible to do an MRI of the hand within 0-2 days, a negative MRI can justify to remove the cast immediately. Patients won't have to be in a cast for 10 days and might have an earlier return to work.

We want to find out whether the new protocol (with a fast MRI) is more cost-effective than the old protocol (with 10 days cast).

In the past, some studies were carried out concerning this cost-effectiveness; these studies did not all however look at the earlier return to work. The results of studies from abroad are not comparable to the Dutch situation however, since different regulations do apply concerning social security and medical costs. In the Netherlands, there are no earlier studies conducted comparing the costs, return to work and functioning of the hand in this field.

Study objective

We want to find out whether the new protocol (with a fast MRI) is more cost-effective than the current protocol (consisting of 10 days cast).

Primary Objective: To find out whether the new MRI protocol is more cost-effective than the old protocol.

Secondary Objective(s): To assess the patient's functioning of the hand after 6 weeks, and compare between 2 days cast (MRI) and 10 days cast (current protocol).

Study design

We will conduct a prospective randomized controlled trial.

Patients attending the ER or radiology department with a suspected scaphoid fracture (with a negative X-ray) will be randomized. One group will be treated by current protocol (10 days cast, second X-ray), the other group will get a fast MRI, if the MRI shows no fracture the cast will be removed immediately. Patients in the MRI group will be seen for revision after a week, to be sure not to oversee significant other possible injury (muscle contusions etc.)

Randomisation will take place according to week number: patients attending the CSO in even weeks will get an MRI, patient presenting at uneven weeks will be treated by the current protocol.

Study burden and risks

There are no risks, since MRI uses no radiation. No contrast media is used.

Time: 20 minutes.

The benefit for the patient is multiple:

No fracture seen on the MRI (85%): no more cast is needed for 8-10 days.

If a fracture is seen (15%): proper treatment can be started right away.

Time for completion of the questionnaires:10 minutes.

The costs for the MRI will be paid by the department of Radiology, patients will not receive an invoice.

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

patients with a suspected fracture of the scaphoid, with a negative x-ray, age 18-60 years.
Time between trauma and visit to the hospital smaller than one week.

Exclusion criteria

Previous scaphoid fracture at the same side.
Poly-trauma patients.
Contra-indications regarding MRI.
Joint diseases like reumatoid arthritis.
Insufficient command of the Dutch language.

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	08-01-2013
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO	
Date:	12-09-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	26-03-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	21-04-2016

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	10-02-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL38979.042.12