DASH score Study for distal radial fractures

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1 to get a data base on the functional out come of our current treatment of distal radial fractures. These data base should be used for evaluating future treatment modifications. 2. Evaluate the DASH score. In any score system not al questions...

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

Summary

ID

NL-OMON29775

Source
ToetsingOnline

Brief title
DASH score Study for distal radial fractures

Condition

- Fractures
- Bone and joint therapeutic procedures

Synonym
distal radial fracture

Research involving
Human

Sponsors and support

Primary sponsor: Máxima Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: DASH, distal radial fractures

Outcome measures

Primary outcome

DASH score during follow-up

IRT calibration of the DASH score

Secondary outcome

1 Is there a relation between the first two levels of AO classification and the

DASH score?

2 How is the relation between the DASH score of the Lidström excellent and

non-excellent group?

3 Is there correlation between the DASAH score and the Lidström score?

4 how does the Lidstrom score behave during the follow-up of distal radial

fractures?

Study description

Background summary

The distal radial fracture is a common type of fracture especially in elderly patients. fifteen percent of al fractures in patients over 65 years of age are distal radial fractures. In 1997 42.000 patients were diagnosed, with a total cost of 24 million Euro. There are may studies done to classify the results of distal radial fracture treatment. Also the Cochrane reviews done on distal radial fractures could not reach a conclusion due to the heterogenic populations, the use of different classifications and different in outcome measurements. The DASH score is a validated tool developed by the American academy of Orthopaedic Surgical Council of Musculoskeletal Special Societies (COMSS) and the Institute for Work and Health (Toronto, Ontario). The DASH

score is mend for the whole upper extremity, and reflects daily activities as functional outcome.

Study objective

1 to get a data base on the functional out come of our current treatment of distal radial fractures. These data base should be used for evaluating future treatment modifications.
2. Evaluate the DASH score. In any score system not al questions contribute equally to the finale score. We want to calibrate the DASH score.

Study design

There are 4 measurements moments for one patient.

First the intake moment when the distal radial fracture is diagnosed. Here the DASH score reflecting the pre-accident state is taken.
the DASH scores are repeated at 3 months, 6 months and finally at 12 months including a final X-ray at 12 months.
The treatment of the distal radial fracture is according the standard treatment protocol and not subject of this study.

Study burden and risks

First time is needed to do the DASH questionnaire. This is estimated at 10 minutes per time and 20 minutes for the first intake. Total time asked fro the patient is 1 hour during the year of the study.
The potential harm from one time extra X ray's of the distal radius is so low that it may be neglected.
The extra X-ray's after one year a necessary to confirm the bone position after one year of follow-up.

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 unilateral distal radial fracture, age 18 years or older

Exclusion criteria

distal radial fracture on both sides
a history of distal radial operations / deformaties

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2007
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	18-07-2006
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL12648.015.06