Differences in DASH Scores across American, Dutch and South American Subjects treated for Radial Head and Distal Radius Fractures: a Multicenter Trial

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To test the hypothesis that patients who do understand the importance of tolerance of pain to regain motion after a radius fracture, do better than patients who don't understand, in terms of motion and DASH scores at follow-up. Secondarily, to...

Ethical review	Approved WMO
Status	Pending
Health condition type	Bone and joint therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON30809

Source
ToetsingOnline

Brief title
International differences in DASH Scores after radius fractures

Condition

- Bone and joint therapeutic procedures

Synonym
forearm fracture, radius fracture

Research involving
Human

Sponsors and support

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

Intervention

Keyword: DASH, fractures, pain, radius

Outcome measures

Primary outcome

Rated agreement with "No pain, no gain" statement

Elbow function (degrees) for radial head fractures

Wrist Function (degrees) for distal radius fractures

Secondary outcome

DASH scores

CES-D scores

PCS scores

Study description

Background summary

Psychological and personality factors, such as pain anxiety, catastrophizing, and depression are strongly related to upper extremity specific health status and may also influence recovery. Fractures of the distal radius and radial head often lead to limitation of function. We believe that subjects who understand that tolerance of pain is necessary for good recovery from this injury will do better, whereas subjects that fear pain and believe that they are harming themselves when they do exercises that cause pain can develop permanent stiffness.

Study objective

To test the hypothesis that patients who do understand the importance of tolerance of pain to regain motion after a radius fracture, do better than

patients who don't understand, in terms of motion and DASH scores at follow-up.
Secondarily, to evaluate the influence of psychosocial factors and cultural difference on both objective (motion, grip strength) and subjective (DASH questionnaire) measures of functional recovery.

Study design

All subjects that fit inclusion and exclusion criteria will be invited to enroll. The treating physician/investigator will inform patients about the study during initial visit at the outpatient clinic. The study will be described in detail and informed consent will be obtained by the research fellow during the next follow-up visit. It will be emphasized that participation is voluntary.

Subjects will be asked to fill out questionnaires (DASH, CES-D, DLV-IV) and get a physical examination at their standard follow-up appointment with the treating surgeon (distal radius: at 6 and 12 weeks, radial head: at 4 weeks). In addition, subjects will be asked to rate their agreement with the following statement with respect to recovery from their injury: *No pain, no gain*, with use of a 5-point Likert scale.

Study burden and risks

Subjects may be bothered by having to complete questionnaires. Some of the questions on the psychological questionnaires may make subjects feel uncomfortable. Subjects will not be obligated to answer and psychological or psychiatric counseling will be available to subjects if necessary. Little benefit is expected to participating individuals. Rather the benefit will be to society, as this research will better define the role of cultural differences and attitude toward pain in the rehabilitation after a radial head or distal radius fracture.

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

1. A non-operatively treated fracture of the radial head or distal radius.
2. Cognitive and physical ability to do exercises.
3. Isolated injury
4. Dutch resident
5. Age > 18 years

Exclusion criteria

1. pregnant women
2. patients that are unable to give informed consent

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2006
Enrollment:	160
Type:	Anticipated

Ethics review

Approved WMO

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	NL15255.018.06