Early vs. delayed physical therapy (exercises) for non-operatively treated proximal humerus fractures: A multicenter prospective randomized trial

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

Summary

ID

NL-OMON37614

Source
ToetsingOnline

Brief title
ELEPHANT-trial

Condition

- Fractures

Synonym
Proximal Humerus Fracture/Fracture of the upper arm

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Geen geldstroom

Intervention

Keyword: DASH and Constant instruments, Non-operative treatment, Proximal humerus fracture, Rehabilitation

Outcome measures

Primary outcome

The primary outcome variable will be the shoulder forward flexion.

Secondary outcome

The secondary outcome variables include shoulder pain, Likert scores, external

and internal rotation, shoulder abduction, DASH and Constant scores.

Study description

Background summary

Proximal humerus fractures with limited displacement and fractures that occur in older, less active or infirm patients are treated non-operatively .There is a general impression, supported by some data, that better function is obtained with immediate initiation of shoulder exercises. However, there is some concern that this may contribute to nonunion of the fracture and may be unnecessary. Some researchers have demonstrated better outcomes with immediate rehabilitation with pendulum movements. Others have shown similar functional outcomes when rehabilitation begins approximately a month after injury, or when radiographs show signs of bone healing, and this delay is associated with lower rates of non-union and malunion occurrence.

The Hand and Upper Extremity Unit of the Massachusetts General Hospital (MGH) is a referral center for complex post-traumatic problems and therefore sees many patients with a proximal humerus non-union that have been referred from peripheral hospitals. It is possible that a concern regarding a so-called *frozen shoulder* may be leading surgeons to recommend initiation of exercises too early resulting in healing problems. The surgeons of the MGH Orthopaedic Hand and Upper extremity service believe that more data is needed with regard to this question and have started a prospective comparative trial between immediate and delayed exercises for regaining shoulder motion after proximal humerus fracture.

The Trauma Unit of the Academic Medical Center in Amsterdam agrees with the necessity for more data regarding this matter, has been invited by the MGH to collaborate on this study, and would like to be added as a study site to be able to enroll patients in this trial, turning it into a multicenter trial.

Study objective

The main objective is to analyse whether or not active forward flexion of the shoulder six months after non-operative treatment of a proximal humerus fracture is better when physical therapy is initiated directly (within 3 weeks after injury and before fracture healing has become established) than when it is initiated between 4 and 8 weeks after injury (when early fracture healing is apparent clinically and/or radiographically).

The secondary objective is to determine if there are differences in several functional outcome measures (DASH, Likert Score, Constant score, abduction, internal and external rotation) six months after fracture between the two groups.

Study design

This study is a prospective, randomized controlled clinical trial comparing two treatment options; early vs. late physisical therapy in nonoperatively treated patients with proximal humerus fractures.

Intervention

One group receives physical therapy immediately (within 3 weeks after injury), the other group receives physical therapy once healing has occurred clinically and/or radiographically (4-8 weeks after injury).

Study burden and risks

The treatment that patients will receive is the standard treatment of care in the United States, which currently depends on the surgeon*s preference to write a prescription for physical therapy (or instruct patients to begin moving the arm) to start either immediately (within 3 weeks of injury) or not until early healing is established (between 4 and 8 weeks after injury) as determined by the treating surgeon by examination and radiographs. In the Netherlands the standard treatment usually consists of a direct start of the shoulder excersises. Both start dates are likely to benefit the patients and both are considered standard treatment in the United States depending on the physician*s preference. In the Netherlands, as previously stated, a direct start of shoulder excercises is generally considered the standard treatment of care. Further benefit will be to future patients with this problem as this data may improve understanding of this illness.

Patients will have to fill in a DASH form during all three visits (enrollment and two follow-up dates) which will take approximately 10 minutes of their time, depending on how fast they can read. The assessment of the range of motion of the shoulder will take approximately five minutes during the second and third follow-up visits. The quantity and type of pain medication used will be asked and registered.
The risks are comparable to those that the standard treatment involves. Close follow up and a protocol of treatment, identical to the standard one, will be applied in every subject. Reduction of risks will be done according to inclusion and exclusion criteria.
If complications arise, the treating physician will proportionate the adequate treatment according to the current protocols of treatment based on the published literature.

Subjects could experience mild discomfort during physical examination and testing, but this will be no different from physical examination during routine follow-up.

There will be no direct benefit to patients enrolled in the trial. We expect society as a whole to benefit from better evidence for determining the choice of rehabilitation protocol.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1100 DD Amsterdam
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1100 DD Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Older than 18y
Diagnosed with proximal humeral fracture clinically and confirmed by imaging studies (X rays and/or CT Scans)
Any type of proximal humeral fracture according to the Neer or AO classification system.
Non-operative treatment elected

Exclusion criteria

Younger than 18 y.
Multiple other fractures.
Patients that have received surgical treatment including closed reduction and percutaneous fixation, open reduction and internal fixation (plates, screws, pins, tension wire bands, cerclage wiring and/or intramedullary nailing) and/or articular shoulder prosthesis.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	21-05-2012
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	15-03-2012
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
ClinicalTrials.gov	NCT00438633
CCMO	NL39341.018.11