Complications and Functional Outcomes after Subcapital Humerus Fractures

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

Summary

ID

NL-OMON49294

Source
ToetsingOnline

Brief title
SURF study

Condition

- Fractures

Synonym
broken shoulder, subcapital humerus fracture

Research involving
Human

Sponsors and support

Primary sponsor: OLVG
Source(s) of monetary or material Support: Stichting wetenschappelijk onderzoek OLVG

Intervention

Keyword: 2- part surgical neck fracture, Non-operative, Outcomes

Outcome measures

Primary outcome

Primary outcome: the Constant Murley Score. The CMS is a score ranging from 0 to 100 to evaluate the function of both shoulders. A higher score represents a better shoulder function. The CMS consists of four domains: pain (0-15), activities in daily living (0-10), mobility (0-50) and strength (0-25). To determine mobility the pain-free range of shoulder abduction, forward flexion, external rotation and internal rotation is tested. The shoulder strength is measured at 90 degrees in abduction.

Secondary outcome

The following secondary outcomes will be reported for adults and older adults:

• Radiographic outcome: each X-ray image will be assessed by the radiologist for osteoarthritis, non-union (defined as the absence of consolidation 3 months after the initial trauma), fracture consolidation and avascular necrosis. Additionally, the humeral neck- shaft angle will be measured with the shoulder in external rotation.

• Complications: the need for surgical intervention due to failure of non-operative management, nerve injury, chronic pain syndrome, rotator cuff pathology, mal-union (defined as healing of the bone in an abnormal position), non-union and mortality after 1 year.

• The quality of life measured with the EuroQol5D (EQ5D) questionnaire.

• The sleep quality reflected by the Pittsburgh Sleep Quality Index (PSQI)

• The rate of the shoulder as a percentage of normal shoulder function measured with the Single Assessment Numeric Evaluation (SANE).

• The performance of daily activities measured with the Disabilities of the Arm, Shoulder and Hand score (DASH) questionnaire.

Two additional secondary outcomes will be reported for adults (18-65 years).

• Return to sports measured with the DASH score module sports.

• Return to work using the DASH score module work.

Two additional secondary outcomes will be reported for older adults (18-65 years).

• The functional independency reflected measured with the Katz index.

• The ambulation ability of patients measured with the Functional Ambulation Categories (FAC).

Study description

Background summary

Worldwide 6% of all fractures are localized in the proximal humerus and the incidence rate is expected to increase. Proximal humerus fractures (PHF) are strongly associated with osteoporosis and are most frequently observed in the geriatric population, showing a peak incidence of 379 per 100.000 among females above 80 years of age. The mortality rate is 10% and it is considered as one of the major causes for social dependency among older adults. The most common causes of PHF in patients younger than 50 years of age are high-energy traumas and sports related injuries. PHF could have a high impact on daily life activities: patients may be unable to do sports or carry out their work. Treatment options include surgical intervention or non-operative management, depending on the type of fracture, fragment displacement and patient characteristics. Twenty percent of the cases require surgical intervention.

However, a lack of consensus exists on correct indications. Thirteen percent of proximal humerus fractures are subcapital humerus fractures which are most frequently treated non-operatively. Previous studies have reported the outcomes of different surgical techniques, patients sustaining three- or four-part fractures and populations including patients of all ages. However, little is known about outcomes after non-operative treatment of subcapital humerus fractures and few studies have reported a follow-up time of 2 years or longer. It is hypothesized that non-operative treatment of subcapital humerus fractures are associated with good functional outcome scores and a low complication rate. In case satisfactory outcomes are reported surgical costs and intra- and postoperative complications could be prevented.

Study objective

The primary objective is to assess functional shoulder outcome scores and complications after non-operative treatment of subcapital humerus fractures among adults and older adults at least 2 years after the fracture. The secondary objectives are:
1. To assess which factors (e.g. age, comorbidities, ambulation ability, independency in activities of daily living, trauma mechanism) are associated with a difference of more than 10 points between the Constant Murley Score (CMS) of the affected and contralateral shoulder in patients with a subcapital humerus fracture treated non-operatively.
2. To describe the number of patients with a subcapital humerus fracture treated surgically and non-operatively.

It is hypothesized that the difference between the CMS of the affected shoulder and contralateral shoulder is less than 10 points.

Study design

A cross-sectional cohort study will be carried out at OLVG Hospital Amsterdam in the Netherlands.

Study burden and risks

No costs are associated with participation in the study. Costs associated with the radiographs will be covered and participants will be compensated for travel expenses (including parking fees). Participation requires physical efforts: the trip to the hospital, obtaining radiographs, undergoing a shoulder examination and the completion of the questionnaires. The duration of the shoulder examination will be 15 minutes, completing the questionnaires 25 minutes and having the radiographs taken 10 minutes. A potential risk associated with the study is radiation dosage applied in radiography. However, the dosage radiating from the X-ray source is very low and may not cause any adverse health effects: the radiation dosage of two radiographs is 0.08 mSv. As illustration, the

annual background radiation in the Netherlands is ~2.5 mSv. There are no benefits for participating patients. Nevertheless, patients may appreciate having the shoulder examined and checked with additional radiographs. Participation will contribute to increase current knowledge and improve treatment for patients with subcapital humerus fractures.

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 subcapital humerus fractures treated non-operatively are eligible for the study. A subcapital humerus fracture is defined as a two-part surgical neck fracture, regardless of the degree of fragment displacement.
Non-operative treatment includes sling immobilization followed by gradual mobilization. The study will evaluate the results of adults and older adults.

The adult cohort encompasses patients between 18 and 65 years of age. The older adult cohort encompasses patients of at least 65 years of age.

Adults (18- 65 years of age):
Patients with subcapital humerus fractures treated non-operatively and minimum follow up length of 2 years will be included. In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1. Men or women of between 18 and 65 years of age upon the first presentation at the Emergency Department.
2. Written informed consent to participate in the study

Older adults (at least 65 years of age):
Patients with a subcapital humerus fracture treated non-operatively and a minimum follow up length of 2 year will be included. In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1. Men or women of at least 65 years of age upon the first presentation at the Emergency Department.
2. Written informed consent to participate in the study

Exclusion criteria

Adults (18- 65 years of age):
A potential subject who meets any of the following criteria will be excluded from participation in this study:
1. Patients less than 2 years of follow up time (the mean time for bone consolidation is 2 years)
2. Patients presented to the emergency department more than 1 month after injury (a delay in adequate treatment may affect functional shoulder outcomes)
3. Patients with an open fracture
4. Patients with neurovascular injury
5. Patient with concomitant injuries of the affected shoulder
6. Incapacitated patients
7. Patients with a shoulder arthroplasty in the contralateral shoulder
8. Patients with a nerve injury and concomitant motor function impairment of the contralateral shoulder
9. Patients with a medical history of a proximal humerus or clavicle fracture in the contralateral shoulder
10. patients with a severely decreased shoulder function due to any other medical condition of the contralateral shoulder at the time of the outpatient visit

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Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-02-2020
Enrollment:	68
Type:	Actual

Ethics review

Approved WMO

Date:	13-12-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	15-01-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-02-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL71324.100.19