The consequences of independent functioning and public health care of fractures of the proximal humerus and their treatment: A prospective observational study

Published: 20-11-2013
Last updated: 26-04-2024

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

Summary

ID

NL-OMON39255

Source
ToetsingOnline

Brief title
ARM study

Condition

- Fractures
- Bone and joint therapeutic procedures

Synonym
fracture of the shoulder, Proximal humeral fracture

Research involving
Human

Sponsors and support

Primary sponsor: Rijnland Ziekenhuis
Source(s) of monetary or material Support: Er loopt een aanvraag voor subsidie door het Anna fonds

Intervention

Keyword: Costs, Functioning, Health care support, Revalidation

Outcome measures

Primary outcome

Degree of independent functioning is defined as the amount of days a patient needs nurse care or home care. The costs are accurately determined in euros during one year in the Dutch health care system. Functional outcome is assessed using the Dutch validated DASH questionnaire (Veehof 2002) and the Shoulder Function Assesment Scale (van den Ende 1997 / Vermeulen 2005) and EQ-5D and SF-12 as a general health score and cost utility measure.

Secondary outcome

Not applicable.

Study description

Background summary

Several recent studies warn that the incidence of proximal humeral fractures is rising with the expanding ageing population (Palvanen 2006, Kannus 2000, Court-Brown 2006). Also, proximal humeral fractures are known to have severe impact on upper extremity function (Calvo 2010) Therefore it can be expected that the consequences, financially as well as workload, on public healthcare will increase the coming decades. The magnitude of these consequences is likely to be dependent of someone*s ability to function independently.
It is generally accepted that proximal humeral fractures with displacement of more than 1 cm, or angulation (tilt) of more than 45* need operative treatment. But besides the classic work of Neer in 1970, there is still little support for

this advice (Neer 1970, Foruria 2011). Furthermore, in proximal humeral fractures, there are many different fracture patterns, (and classification systems) and thus possible treatment strategies. The choice of which treatment fits best for an individual patient depends on numerous factors, and with lack of randomized comparative trials, decision making is not based on evidence, but only on expert opinion with some support from retrospective studies (i.e. level 3 evidence) (Murray 2011, Handoll 2010).

Study objective

The primary goal is to determine the degree of independent functioning of the patient with a proximal humeral fracture.
A secondary goal is to evaluate all primary and secondary costs during the rehabilitation period after a proximal humeral fracture.
A third goal is to relate healed proximal fractures to patient functioning in a virtual dynamic environment (Krekel 2010).

Study design

A multicentre, prospective observational study.
Treatment options, either conservative or surgical will be made by the present treatment protocols in these centers (i.e. usual care design).

Study burden and risks

The burden of this study consists in the duration of 3 standard outpatient clinic visits which coincide with the regular outpatient visits. All patients need to fill in the questionnaires (15 to 30 minutes per questionnaire), which is extra compared to usual care. An extra CT scan will be made at the end of the treatment period, to evaluate the healed proximal humeral fracture. The patient will be exposed to a very low radiation dose of a maximum of 10 mGy. This amount of radiation has a very little effect on the patient*s health (Hall et all 2007).

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

- A proximal humeral fracture
- Age 50 years and older
- presenting to emergency department of one of the three involved Medical Centres.

Exclusion criteria

- Polytrauma / other associated injuries
- Pre-existing illness affecting the upper limb function
- Unknown date of fracturing or trauma > 3 weeks ago
- Pathological fracture
- Open fracture
- Associated nerve damage
- Unable to fill in a questionnaire
- No possibility of follow up
- No informed consent

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-07-2014
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Date:	20-11-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL40852.058.12