Hip fractures: Inventarisation of Prognostic Factors and their Contribution towards Rehabilitation in older persons

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

Summary

ID

NL-OMON49828

Source
ToetsingOnline

Brief title
HIP-CARE

Condition

- Fractures

Synonym
hip fracture, proximal femoral fracture

Research involving
Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: geriatric rehabilitation, hip fracture, inception cohort, mixed methods design

Outcome measures

Primary outcome

The main study objective for the three combined research focusses of HIP CARE is to determine if there are prognostic factors which may have influence on successful geriatric rehabilitation after one year, which is operationalized in terms of survival, residing in pre-fracture home situation, and functional recovery

Informal caregivers:

• Quality of life

• Caregiver strain

Secondary outcome

Patients

• General activities-of daily-living (ADL): Katz-ADL

• Daily life activity Lawton iADL

• Quantification function of the hip: Harris hips score (HHS)

• Generic health-related quality of life (EQ-5D-5L)

• Healthcare utilisation

• Social functioning (loneliness)

Caregivers

• Social functioning (loneliness)

Determinants for patients

• Patient and informal caregiver characteristics

• Short Physical Performance Battery (SPPB)

• 1-item fear of falling (FOF)

• Falls efficacy scale international (FESi-7)

• GARVAN bone fracture risk calculation

• Functional Comorbidity Index (FCI)

• Accelerometer: measures mobility during the course of a 7 days

• Hand grip force (HGF)

• Hospital anxiety and depression scale (HADS)

• Fat free mass index (FFMI)

• Routine healthcare data GP five years before and two years after surgery

(using ELAN)

• Living situation

• Cognitive screening

• Nutritional status

• Complications

• Coping at baseline

Determinants for caregivers

• Proxy Fear of falling

• Coping at baseline

• Anxiety and depression

Study description

Background summary

Hip fracture is a major cause for mortality and morbidity in elderly persons with an incidence of 17,000 in 2016. Beacuse of the incrasing age it is expected that the number of hip fracture patients will increase. They form a frail population. Patients with hip fracture have a mean age of 82 years, almost 75% of their patients are women, nearly 70% has at least two chronic illnesses , and they experience on average 3 complications 25% mortality rate and only 40-60% chance of complete functional recovery in the first year after fracture.

After the acute hospital phase, patients that had a previous independent living situation are either discharged home or to an inpatient geriatric rehabilitation(GR) in post-acute GR wards where they treated by a multidisciplinary team consisting of an elderly care physician , physical therapist, occupational therapist, psychologist and skilled nurse. Currently there are no clear guidelines determining type, quality, or intensity during rehabilitation admission. Also, the effect of quality and intensity as well as important (age related) characteristic on functional outcome and quality of life are unknown.

Other factors that are related to the success of geriatric rehabilitation after a hip fracture include coping behaviour and psychosocial factors such as depression and fear of falling and the way therapist can handle these personal factors. The presence of an informal caregivers is probably an important success factor in rehabilitation after hip fracture.

Study objective

In this study we aim to investigate prognostic factors by adding extra questionnaires for patients and their caregivers, observation list and the use of an accelerometer. These variables can provide information about the successful as well as non-successful rehabilitation process and explore effective treatment programmes with the purpose of developing good care-pathways. In order to develop these care-pathways, it is important to gather information about patient-related factors, healthcare use during and after admission to post-acute GR wards as well as caregiver burden and quality of life

Study design

A mixed-method approach with a large inception cohort and qualitative data-collection from surgeons/orthopaedic surgeons , elderly care physicians,

physical therapists, patients and primary care givers

Study burden and risks

In the post- operative fase the patient and care giver will be given information about the study.
The patient has 24-48 hours to think about the study. After this period the researcher will supply verbal information and if agreed the informed consent will be signed. There are questionnaire during the post- operative phase for both patients and care givers The is time consuming for the patient and his/her caregiver.

During the follow upt there are no additional check ups beside the regular outpatient check-ups causing no additional burden to the patient. The burden of participating is time investment due to the additional questionnaires that must be filled in combination with the usual care given. The out patient check will therefore be extende by 30 minutes.

During the 3 month control the patient will be fitted for an accelerometer for 7 days. Previous studies show that the burden is minimal.
For the patients in the follow up fase who cannot come to the outpatient check-up the researcher will conducted the investigation at their home or in the nursing home. This too is a burden of time investing for the patient and his/her caregiver.

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

patienten:
> 70 years, admitted to HMC Bronovo for acute hip fracture, Only patients eligible for (geriatric) rehabilitation. , informal caregivers:
family member or other natural person who normally provides the daily care or super-vision of the patient with a hip fracture,

Exclusion criteria

patients:
<70 years, residing in a nursing home before the hip fracture, unwilling to provide informed
consent, unable to provide informed consent and insufficient mastery of the Dutch language. Pathological hip fractures, informal caregivers:
• Insufficient mastery of the Dutch language
• Unable to provide informed consent
• Unwilling to provide informed consent.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	19-12-2018
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Date:	30-11-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	08-12-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	27-11-2020
Application type:	Amendment
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	NL66871.098.18