A prospective multicenter cohort study to evaluate the benefit of the geriatric fracture center (GFC) concept * Evaluation of a geriatric co-management program

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To investigate the effect of a GFC regarding major adverse events (AE) with a relationship to the treatment / residential status / immobilization (as defined under "Primary outcome measures") from surgery to a 36 month follow-up.

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

Summary

ID

NL-OMON45115

Source
ToetsingOnline

Brief title
Evaluation of a Geriatric Co-management Program

Condition

- Fractures

Synonym
hip fracture

Research involving
Human

Sponsors and support

Primary sponsor: AO Documentation and Publishing Foundation, Clinical Investigation and Documentation
Source(s) of monetary or material Support: Ministerie van OC&W,AO Clinical Investigation and Documentation;Duebendorf;Zwitserland

Intervention

Keyword: Co-management, Fracture, Geriatrics

Outcome measures

Primary outcome

Smaller proportion of patients with at least one major AE related to treatment

/ residential status / immobilization (as defined below) in the GFC group

compared to the UCC group.

AEs related to treatment / residential status / immobilization include and are

limited to:

- Delirium

- Congestive heart failure

*- Pneumonia

*- Deep venous thrombosis

*- Pulmonary embolism

*- Pressure ulcers

*- Myocardial infarction

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Secondary outcome

- Any other AE not mentioned under primary measure(s) as well as its

relationship to the treatment /residential status / immobilization

*- Activities of daily living

o Modified Barthel index pre-injury, at12 weeks and 12 months

*- Number of re-admissions to an acute hospital

*- Mobility

o Timedupandgotest(TUG) at 12 weeks and12 months

o Parker Mobility Score pre-injury, at 12 weeks and 12 months

*- Number of falls

*- Pain using a Numeric Rating Scale

*- Residential status pre-injury, at discharge, at 12 weeks and 12 months

*- Quality-of-life

o EQ-5D questionnaire at 12 weeks and 12 months

*- Mortality

*- Time from admission to start of pain medication management

*- Time from admission to start of fluid management

*- Time from admission to surgery

*- Time from surgery to discharge

- Number of patients receiving adequate secondary fracture prevention medication

*- Medication

o Number of different types of medication at admission, discharge 1, 12

weeks, 12 months

o Information whether analgesics, osteoporosis and other medications are

administered at all study visit time points

*- Number of patients for which the nutrition status was evaluated / adapted

- Occurrence of a contralateral hip fracture

*- Direct and indirect costs

Study description

Background summary

The number of geriatric trauma patients is rapidly increasing. Fragility fractures and their care are a challenge to health care systems and societies. In 1990, the WHO estimated a worldwide occurrence of 1.3*1.6 million osteoporotic hip fractures and predicted an increase to 4 million per year by 2025, with the largest number occurring in Asia. Because of multiple comorbidities, treatment of geriatric fracture patients showed to be associated with a high number of complications. Different ortho-geriatric concepts have been developed to improve patient*s outcome. Until now, the beneficial effect of these models could not be proven. There are great costs related to geriatric trauma. The current care is often sub-optimal. Fracture services often fail to respond to the true complexity of their older patients* needs * for detailed medical and rehabilitation care as well as surgery.
The scope of a geriatric co-management program is to improve both the quality and cost-effectiveness of fracture treatment in geriatric patients. Care pathways and co-management of geriatric hip fracture patients need to be further evaluated in order to demonstrate the effect of interdisciplinary geriatric interventions identification of such patients who need specific medical or multidisciplinary attention.

Study objective

To investigate the effect of a GFC regarding major adverse events (AE) with a relationship to the treatment / residential status / immobilization (as defined under "Primary outcome measures") from surgery to a 36 month follow-up.

Study design

Prospective multicenter cohort observational study

Study burden and risks

The risk of specific complications during participation of the study is low, despite the high number of complications during standard treatment. The study comprises a registration and data management so no risks are involved in participating in the trial itself. No additional ionizing radiation is necessary, as the follow-up visits are standard of care. It is expected that added measurements in this study will take 2 times 15 minutes and a telephone

call at 3 years of 10 minutes.

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

Preoperative Inclusion Criteria:
Age * 70 years
Geriatric patients with hip fractures Treated either with Osteosynthesis or Endoprosthesis
Ability of the patient or assigned representative to understand the content of the patient information / Informed Consent Form
Signed and dated Institutional Review Board (IRB) / Ethics Committee (EC)-approved written informed consent

Exclusion criteria

Preoperative Exclusion Criteria:
Recent history of substance abuse (ie, recreational drugs, alcohol) that would preclude reliable assessment
Prisoner
Participation in any other medical device or medicinal product study within the previous month that could influence the results of the present study

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2015
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	17-12-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-06-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit

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	NCT02297581
CCMO	NL52759.068.15