The value of nonoperative versus operative treatment of frail institutionalized elderly patient with a hip fracture in the shade of life (FRAIL-HIP); a multicenter observational study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23054

Source
NTR

Brief title
FRAIL-HIP

Health condition

Proximal femoral fracture

Sponsors and support

Primary sponsor: Noordwest Ziekenhuisgroep, Department of Surgery
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Quality of life, measured with the EuroQoL-5D

Secondary outcome

Quality of life measured with the QUALIDEM; pain and pain medication; satisfaction of patient (or proxy) and caregivers with the management approach; time to death; direct medical costs.

Study description

Background summary

BACKGROUND

A proximal femoral fracture is strongly associated with mortality. Mortality is highest among elderly with both physical and cognitive comorbidities. There are no strict guidelines on whether or not to operate these patients. NICE advises to discuss if patients are open to hospital admission and possible surgery, and Dutch guidelines advocate operative treatment in patients with a life expectancy beyond six weeks. Common practice is to decide on treatment based on shared decision, yet nonoperative management is not commonly used. Practice variation occurs, and it remains unknown if nonoperative treatment would result in at least the same quality of life of femoral fracture patients who are institutionalized and have a limited life expectancy. Treatment decision will be reached following a structured shared decision process, in which pros and cons of both operative and nonoperative management are discussed with patients, their relatives, and all relevant care providers involved.

AIM

The primary aim is to determine the effect of nonoperative management versus operative management on the quality of life (EQ-5D) until six months in frail institutionalized elderly with a limited life expectancy who fracture their proximal femur. Secondary aims are to determine the effect of nonoperative management versus operative management on the quality of life (QUALIDEM), level of pain (PACSLAC-D) and use of analgesic medication, rate of complications, time to death, the satisfaction of the patient’s relatives and caregiver with the management strategy and health care consumption (with associated costs) in these patients. The ultimate aim is to determine the cost-efficacy of nonoperative management versus operative management in these patients.

STUDY DESIGN

Multicenter, observational cohort study.

POPULATION

Frail institutionalized elderly (70 years or older who have a body mass index <18.5, a Functional Ambulation Category of 2 or lower pre-trauma, or an ASA 4-5), who sustained a proximal femoral fracture.

INTERVENTION

Following a structured shared decision process, patients and treating physicians will decide on the best treatment for each individual patient. This will be:

1) Nonoperative management

2) Operative management

ENDPOINTS

Primary outcome measure: quality of life (EQ-5D).

Secondary outcome measures: quality of life (QUALIDEM); pain and pain medication; satisfaction of patient (or proxy) and caregivers with the management approach; time to death; and direct medical costs.

Data will be collected at 7, 14, and 30 days, and 3 and 6 months after trauma.

RECRUITING COUNTRIES

The Netherlands

Study objective

We expect that quality of life after nonoperative treatment is at least as good as after operative treatment.

Study design

Seven, 14, and 30 days, and 3 and 6 months after trauma.

Intervention

Patients in the intervention group will be treated nonoperatively. The control group will

receive operative management.

Contacts

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Eligibility criteria

Inclusion criteria

1) Frail institutionalized elderly person (i.e., 70 years or older, living in a nursing home pretrauma, who either are malnutritioned (cachexia of BMI<18.5 kg/m2), or had mobility issues (FAC 2 or less), or have an ASA class of 4 or 5)

2) Acute proximal femoral fracture, confirmed on X-ray or CT-scan

3) Informed consent by patient, or by proxy in patients with mental impairment

Exclusion criteria

1) Bilateral proximal femoral fractures

2) Periprosthetic fracture

3) Fracture diagnosed > 7 days after trauma

4) Patients with a known metastatic disease and a confirmed pathological fracture of the proximal femur

5) Insufficient comprehension of Dutch language to understand rehabilitation programs and other treatment information (this applies to the person signing consent, being either the patient or proxy)

6) Participation in another surgical intervention or drug study that might influence any of the outcome parameters

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2018
Enrollment:	160
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-05-2018
Application type:	First submission

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
NTR-new	NL7040
NTR-old	NTR7245
Other	: 018.208 (METC VUmc)

Study results

Summary results
None yet; study is ongoing