

# 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

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

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Observationeel onderzoek, zonder invasieve metingen

## Samenvatting

### ID

NL-OMON23054

### Bron

NTR

### Verkorte titel

FRAIL-HIP

### Aandoening

Proximal femoral fracture

### Ondersteuning

**Primaire sponsor:** Noordwest Ziekenhuisgroep, Department of Surgery

**Overige ondersteuning:** ZonMw

### Onderzoeksproduct en/of interventie

# Uitkomstmaten

## Primaire uitkomstmaten

Quality of life, measured with the EuroQoL-5D

## Toelichting onderzoek

### Achtergrond van het onderzoek

#### 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

## **Doel van het onderzoek**

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

## **Onderzoeksopzet**

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

## **Onderzoeksproduct en/of interventie**

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

## Contactpersonen

### Publiek

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 1) Frail institutionalized elderly person (i.e., 70 years or older, living in a nursing home pretrauma, who either are malnourished (cachexia of BMI<18.5 kg/m<sup>2</sup>), 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

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

## Onderzoeksopzet

### Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

### Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-09-2018
Aantal proefpersonen:	160
Type:	Verwachte startdatum

## Ethische beoordeling

Positief advies	
Datum:	30-05-2018

Soort:

Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

Register	ID
NTR-new	NL7040
NTR-old	NTR7245
Ander register	: 018.208 (METC VUmc)

## Resultaten

### Samenvatting resultaten

None yet; study is ongoing