

Treatment satisfaction with nonoperative management of suspected hip fractures in nursing home patients; a multicenter prospective case series

No registrations found.

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

Summary

ID

NL-OMON22215

Source

Nationaal Trial Register

Brief title

NONU-HIP

Health condition

Hip fracture

Sponsors and support

Primary sponsor: Noordwest Ziekenhuisgroep, department of surgery

Source(s) of monetary or material Support: Noordwest Ziekenhuisgroep, Foreest Medical School

Intervention

Outcome measures

Primary outcome

EuroQoL-5D (EQ-5D).

Secondary outcome

- Satisfaction of the patient (or proxy) with the nonoperative treatment (0-10 Numeric Rating Scale).
- Satisfaction of the patient's treating elderly care physician with the nonoperative treatment (0-10 Numeric Rating Scale)
- Quality of life: QUALIDEM (DL010) measures quality of life in persons with dementia (regardless of severity) who live in a nursing home or elderly care facility.⁵ It is completed by the medical staff.
- Level of pain: The Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC) is a clinically useful scale for assessing pain in patients with dementia.⁶ It is completed by medical staff.
- Discomfort and agitation/restlessness: the Neuropsychiatric Inventory Questionnaire (NPI-Q) will be used to address this issue. It is completed by the medical staff.⁷ A Dutch translation will be used.
- Amount of analgesic medications used: Daily narcotic use will be calculated using the equivalence scale for 30 mg/day oral morphine.
- Complications: Complications will be categorized for level of severity and treatment necessity according to the Clavien-Dindo classification
- Quality of Dying and Death (QODD): This is a 17-item interview-based questionnaire asking about 17 end-of-life priorities.⁸ This interview is with next of kin.

Study description

Background summary

Hip fractures in nursing home patients are associated with poor outcome with regards to regaining pre-fracture functioning and mortality.¹ Comparative studies with regards to Quality of Life (QoL) in operative and nonoperative treatment for hip fracture patients are non-existent.² Hospital admission and especially surgery often results in cognitive decline, delirium, and complications in frail elderly. In some nursing home patients in the shade of life, the decision is made for nonoperative treatment via advanced care planning or in consultation with legal representatives at the time of a suspected fracture, and consequently the patient will not be referred to a hospital for diagnostics or treatment. However, the outcome of nonoperative treatment with regards to the quality of life, nursability, and satisfaction of caregivers and relatives are unknown. Outcomes of this treatment are needed in order to aid further decision making, advanced care planning, and expectation management in this specific hip fracture patient group with a limited life expectancy. This observational multicenter prospective case series will aim to determine the effect of non-operative management in frail nursing home patients with a suspected hip fracture on to QoL (EuroQOL-5d (EQ-5D), and treatment satisfaction.

Study objective

We expect that treatment satisfaction, quality of life and nursability after nonoperative treatment of a suspected hip fracture in nursing home patients not reffered to the hospital is regarded as satisfactory.

Study design

day 3, 1 week, 2, 4 and 12 weeks post trauma

Intervention

Questionnaires

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

- Permanent residency in a nursing home
- Aged ≥ 65 years old
- Suspected hip fracture, as judged by the elderly care physician (i.e., shortened and exorotated leg, painful greater trochanter/groin upon palpation, unable to bear weight and/or to mobilize)
- Decision to provide nonoperative treatment at the nursing home without referral to a hospital
- Provision of informed consent by patient or legal representative within four days after sustaining the suspected hip fracture

Exclusion criteria

- Insufficient comprehension of Dutch language to understand treatment information (this applies to the person signing consent, being either the patient or proxy)
- 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:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-10-2019
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description

N/A

Ethics review

Positive opinion	
Date:	02-09-2019
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	NL8012
Other	METC VUmc : 2019.343

Study results

Summary results

None yet; study is ongoing