Perioperative indicators for complications and early mortality following hip fracture surgery. The protocol of the Rotterdam hip fracture study.

No registrations found.

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

Summary

ID

NL-OMON21283

Source
NTR

Brief title
FAMMI

Health condition

Patient with hip fractures

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

Hip fracture clinical outcomes and 30-day mortality rate and development of a more specific 30-day mortality prediction tool for clinical usage.

Secondary outcome

- Epidemiological data about the background and incidence of patients with a hip fracture

- Treatment characteristics: clinical outcomes such as; in hospital mortality, length of hospital stay and complications after surgery to gain a more complete insight in the postoperative outcome.

- Treatment costs

- Monitor the implementation and functioning of a geriatric trauma unit within orthopaedic trauma units.

Study description

Background summary

Background:
The primary aim of the present study is to validate earlier suggested risk factors and find new associated factors for 30-day mortality. Secondary aims are;
• Collect epidemiological data about the background and incidence of patients with a hip fracture in the Rotterdam area between 2018 and 2022.
• Analyse clinical outcomes such as; in hospital mortality, length of hospital stay and complications after surgery to gain a more complete insight in the postoperative outcome.
• Monitor the implementation and functioning of a geriatric trauma unit within orthopaedic trauma units.
• Develop a more specific 30-day mortality prediction tool compared to the NHFS (Nottingham hip fracture score) for clinical usage.

Study design and population:
• Multicenter, prospective, observational study
• All patients over 65 years of age, with an acute proximal hip fracture (intracapsular, trochanteric or subtrochanteric) are included.
Excluded are patients with multi trauma injuries, pathologic fractures without sufficient trauma mechanism, or patients with no understanding of the Dutch or English language

Study objective

Early post-operative mortality is particularly high, with reported 30-day mortality rates of 7.5 - 13.3%.
Up to 5% of the hip fracture surgeries is performed in patients with a high death within 30-

days after surgery. If the preoperative mortality risk calculation is more precise, surgery can be avoided in a select patient group.

Study design

30 days, 3 months and 12 months after hospital admission.

Intervention

none

Contacts

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Eligibility criteria

Inclusion criteria

All patients over 65 years of age, with an acute proximal hip fracture (intracapsular, trochanteric or subtrochanteric) are included.

Exclusion criteria

Excluded are patients with multi trauma injuries, pathologic fractures without sufficient trauma mechanism, or patients with no understanding of the Dutch or English language

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):	01-01-2018
Enrollment:	2500
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
N/A

Ethics review

Positive opinion

Date:	14-01-2020
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	NL8313
Other	TWOR. METC Maastad / Ikazia hospital. N-WMO notification : MEC-2017-35

Study results

Summary results
Perioperative indicators for complications and early mortality following hip fracture surgery. The protocol of the Rotterdam hip fracture study.

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