

# Patient Safety and Complex Care.

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The rate of unintended events and avoidable harm for elderly hip fracture patients can be reduced by the introduction of three integrated interventions directed at the structure of the handover process, the role of the patient in the care process...

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving gestopt
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON20906

### Bron

NTR

### Verkorte titel

Patient Safety and Complex Care

### Aandoening

Hip Fracture (heupfractuur)

Functional mobility (functionele mobiliteit) Unintended events (onbedoelde gebeurtenissen)

Avoidable harm (vermijdbare schade)

### Ondersteuning

**Primaire sponsor:** NIVEL and EMGO Institute/VUmc

**Overige ondersteuning:** ZonMw (the Netherlands organisation for health research and development) and Orde van Medisch Specialisten (Association of medical specialists)

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

- Avoidable harm<br>

- Mortality rate within 6 months after discharge<br>
- Unintended events<br>
- Functional mobility<br><br>

Methods: Patient record review and interviews with the patient two weeks and six months after discharge

## Toelichting onderzoek

### Achtergrond van het onderzoek

Elderly patients with a hip fracture are the focus of the research program 'Patient Safety and Complex Care'. It is hypothesized that an improvement in the handover process, a more active role for the patient in the care process and evidence based information for the period after discharge can reduce the rate of unintended events and avoidable harm in this patient group. Patients will be randomly assigned to one of four intervention groups, the control group will receive no interventions. During one year a maximum of 500 patients will be included in the study, the patients have to be 65 years or older and have an acute hip fracture. Pathological fractures, patients who receive no surgery for the fracture, patients participating in other (interfering) intervention studies and patients suffering from dementia will be excluded from the study. The effectiveness of the intervention program will be measured through observations, patient record review and interviews with patients. Primary outcome measures are avoidable harm, mortality rate, unintended events and functional mobility.

### Doel van het onderzoek

The rate of unintended events and avoidable harm for elderly hip fracture patients can be reduced by the introduction of three integrated interventions directed at the structure of the handover process, the role of the patient in the care process and evidence based information for the period after discharge.

### Onderzoeksopzet

- Baseline measurement
- Final measurements (record review six months after discharge, interview with patients (by telephone) two weeks and six months after discharge

### Onderzoeksproduct en/of interventie

Interventions

- SBAR communication tool to structure handover process

- Patient safety card
- Bundles with evidence based recommendations for the period after discharge

There are four different intervention groups (the patients will be randomly assigned to one of the four intervention groups):

Group 1: SBAR

Group 2: SBAR and patient safety card

Group 3: SBAR and bundles

Group 4: SBAR, patient safety card and bundles

Control group: receives no interventions

At least 100 patients per group will be included

## Contactpersonen

### Publiek

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### Wetenschappelijk

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## Deelname eisen

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

1. Acute hip fracture patient
2. 65 years and older

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

1. Pathological fractures
2. Patient receives no surgery for the hip fracture
3. Patient is participating in another intervention study that interferes with this research
4. Suffering from dementia

## Onderzoeksopzet

### Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

## Deelname

Nederland  
Status: Werving gestopt  
(Verwachte) startdatum: 13-06-2008  
Aantal proefpersonen: 500  
Type: Werkelijke startdatum

## Ethische beoordeling

Positief advies  
Datum: 26-11-2008  
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	NL1492
NTR-old	NTR1562
Ander register	ZonMw : 80-81600-98-2-003
ISRCTN	ISRCTN wordt niet meer aangevraagd

## Resultaten

### Samenvatting resultaten

N/A