# Fluoroscopy in hipsurgery: Does manual control of the fluoroscope by the traumasurgeon lead to shorter fluoroscopy time?

Published: 23-11-2011
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To determine wether surgeon-controlled fluoroscopy leads to a lower fluoroscopy time, during placement of osteosynthesis material in hip fractures.

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Fractures |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON40115

**Source**
ToetsingOnline

**Brief title**
Manual control of fluoroscopy in hipsurgery

### Condition

- Fractures

**Synonym**
broken hip, Hipfracture

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Maasstadziekenhuis
**Source(s) of monetary or material Support:** NVT

## Intervention

**Keyword:** Fluoroscopy, Hip surgery, Manual control

## Outcome measures

### Primary outcome

Fluoroscopy time

### Secondary outcome

Radiation dose

# Study description

### Background summary

X-rays, used in fluoroscopy during surgery, has negative effects for patients and surgeons. One way to reduce the radiation dose, is to reduce fluoroscopy time. A few studies report, that surgeon-controlled fluoroscopy reduces fluoroscopy, when compared with radiographer-controlled fluoroscopy. In the Netherlands, the standard is radiographer-controlled fluoroscopy

### Study objective

To determine wether surgeon-controlled fluoroscopy leads to a lower fluoroscopy time, during placement of osteosynthesis material in hip fractures.

### Study design

Patients, undergoing surgery for hip fractures with placement of osteosynthesis material (DHS, CHS or Gamma Nail) will be randomized in 2 groups. In de study group, there will be surgeon-controlled fluoroscopy. In the control group, there will be radiographer-controlled fluoroscopy

### Intervention

Surgeon-controlled fluoroscopy vs. radiographer-controlled fluoroscopy

### Study burden and risks

There is no burden for the patient. The risk is negligible.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

- Age over 18
- Femoral neck, pertrochanteric or subtrochanteric fracture
- Placement, using fluoroscopy, of cannulated hip screws, a dynamic hip screw or Gamma Nail
- Signed informed consent form

## Exclusion criteria

- Pathological fracture
- (Hemi) hip replacement

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |
| Primary purpose: | Diagnostic |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 05-03-2014 |
| Enrollment: | 80 |
| Type: | Actual |

# Ethics review

| | |
|---|---|
| Approved WMO Date: | 23-11-2011 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 30-01-2014 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

# 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 |
| --- | --- |
| CCMO | NL35643.101.11 |