

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 whether 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 whether 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 the 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