

The neurological complications after hip surgery

Published: 19-06-2009

Last updated: 06-05-2024

In this study we want to monitor the neurological complications occurring during hip operations, consisting of hip arthroplasty ('head-neck' prothesis) for traumatic hip fractures. We want to establish that there is more understanding of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fractures
Study type	Observational invasive

Summary

ID

NL-OMON35198

Source

ToetsingOnline

Brief title

The neurological complications after hip surgery

Condition

- Fractures
- Neurological disorders NEC
- Bone and joint therapeutic procedures

Synonym

neurological complications

Research involving

Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis

Source(s) of monetary or material Support: St. Elisabeth Ziekenhuis

Intervention

Keyword: complication, hip surgery, neurology

Outcome measures

Primary outcome

Which neurological complications are seen following hip surgery, in which a 'head-neck' prosthesis is placed, and how often do they occur?

Secondary outcome

Are neurological complications more seen after different surgical techniques?

Is there a relation between the interval of the fracture and the operation in the occurrence of complications?

Study description

Background summary

In literature, various neurological complications are described following hip surgery, divided into two groups of complications namely the central and peripheral nervous system. The main complications of the centrale nervous system are the fat embolism syndrome, delirium and stroke. The main complications of the peripheral nervous system are ischiadic neuropathy, peroneal neuropathy and femoral neuropathy. Other neuropathis, including obturator neuropathy are also described. The previous studies were mainly case reports or series and retrospective studies. There has been no study that has prospectively examined the neurological complications that occur after hip surgery.

Study objective

In this study we want to monitor the neurological complications occurring during hip operations, consisting of hip arthroplasty ('head-neck' prosthesis) for traumatic hip fractures.

We want to establish that there is more understanding of the nature and frequency of these complications. We also want to examine if there are predisposing factors for developing such complications. Examples include: the

nature of the intervention (type of prosthesis and using cement).

Study design

prospective, observational

Study burden and risks

The patients receive hip surgery, following our protocol, which is a regular therapy for their hip complaints. The patient will undergo a neurological physical examination post-operatively and will only undergo further examination on indication, which is also a regular treatment. Because it is a regular treatment, patient will not be exposed to additional risks or have additional burden.

However, the patients without neurological complications during the admission, will also be seen after 8 weeks for neurological follow up. Patients can experience this as an additional burden

Contacts

Public

Sint Elisabeth Ziekenhuis

Hilvarenbeekse Weg 60
5022 GC Tilburg
Nederland

Scientific

Sint Elisabeth Ziekenhuis

Hilvarenbeekse Weg 60
5022 GC Tilburg
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

All patients with hip surgery receiving an arthroplasty of the hip ('head-neck' prothesis) because of a traumatic hip fracture

Exclusion criteria

legally incapable, incapable of giving informed consent

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-10-2009

Enrollment: 100

Type: Actual

Medical products/devices used

Generic name: electromyography on indication;Ct-scan and Mr-scan on indication;electroencephalography on indicatio

Registration: Yes - CE intended use

Ethics review

Approved WMO

Date: 19-06-2009

Application type: First submission

Review commission: METC Brabant (Tilburg)

Approved WMO

Date: 14-04-2010

Application type: Amendment

Review commission: METC Brabant (Tilburg)

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	NL27948.008.09