Spinal morphine in patients with hip fractures to reduce delirium

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The main objective is to decrease the incidence of delirium in patients receiving surgical treatment of a proximal femur fracture with spinal anesthesia.

Ethical review	Approved WMO
Status	Completed
Health condition type	Encephalopathies
Study type	Interventional

Summary

ID

NL-OMON54044

Source
ToetsingOnline

Brief title
SALMON-mind

Condition

- Encephalopathies
- Deliria (incl confusion)
- Bone and joint therapeutic procedures

Synonym
delirium, hip fracture

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis
Source(s) of monetary or material Support: Eigen financiering en verdere financiering wordt gezocht.

Intervention

Keyword: Delirium, Intrathecal morphine, Proximal femur fracture, Spinal anesthesia

Outcome measures

Primary outcome

The incidence of delirium during hospital admission

Secondary outcome

Secondary outcomes are

o Delirium Observation Screening Scale (DOSS)-scores (three times daily),

o pain scores on a Numeric Rating Scale (NRS),

o post-operative opioid consumption,

o post-operative consumption of ondansetron for nausea or pruritus,

o Patient questionnaire with the Quality of Recovery-15 on POD 1 (including

subscales),

o Pruritus-severity score on POD 1,

o time of mobilization after surgery,

o occurrence of complications such as infections, cerebrovascular disorders,

respiratory insufficiency and myocardial injury,

o mortality,

o discharge facility,

o length of hospital stay.

Tertiary outcome is the serum level of NFL on the second post-operative day.

Study description

Background summary

Surgical treatment of proximal femur fractures is complicated by a high incidence of post-operative delirium. Many contributing factors have been identified, most of them are non-modifiable. However, pain and opioid consumption are modifiable factors which may lead to a lower incidence of delirium. An intrathecal injection of morphine may lead to both a reduction in postoperative pain and a reduced opioid consumption. In common practice, the addition of morphine to the spinal anesthesia is commonly used, but depends on the preference of the anesthesiologist. Recently, a retrospective study found that the use of intrathecal morphine was independently associated with a lower incidence of delirium. This has to be confirmed in a prospective study.

Study objective

The main objective is to decrease the incidence of delirium in patients receiving surgical treatment of a proximal femur fracture with spinal anesthesia.

Study design

A double-blinded, placebo-controlled, randomized study.

Intervention

The addition of 100 mcg morphine to the intrathecal injection for spinal anesthesia.

Study burden and risks

The burden constitutes of a questionnaire on day 1 and a blood sample at day 2 to determine the NFL-levels. All other outcome measures are routinely obtained in clinical practise. Spinal anesthesia is the preferred method of anesthesia for these patients in the study hospital.

The risks of receiving intrathecal morphine (intervention group treatment) are a higher incidence of pruritus, nausea, urinary-rentention and a late respiratory depression. Prophylactic measures are installed for pruritus and nausea, which will limit the incidence and severity. All patients will receive a urinary-catheter, which solves the consequences of urinary retention. Late respiratory depression has not been reported with a low dose of intrathecal morphine (<500 mcg). Interaction with routinely administered systemic opioids or benzodiazepines could enhance this complication, and these medications are prohibited on the night after surgery.

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

Proximal femur fracture
Scheduled for surgerical treatment
Spinal anesthesia

Exclusion criteria

Contraindications for spinal anesthesia:
- Coagulation disorders (clopidogrel, INR>1.8, anticoagulation with nadroparine (>100 aXa-IE/kg) or heparine (APTT> 30 sec), recent use of a Direct Oral Anticoagulant, as stated in the guideline *Neuraxisblokkade en antistolling* by the Dutch Society of Anesthesiology.

- Aortic Valve Stenosis of AVA < 1.0 cm2
- Lumbar malformations (local inflammation, lumbar osteosynthesis material, meningocele, tethered cord)
- Inability to retrieve cerebrospinal fluid by lumbar puncture.
Contra-indications for intrathecal morphine:
- Chronic opioid or benzodiazepine use (>1 month daily use).
Other:
- Allergies to amide-type local anesthetics and morphine.
- Patients* refusal
- Patients who are incapable of making decisions regarding anesthesia and no legal representative is available.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	01-03-2022
Enrollment:	364
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Morphine
Generic name:	Morphine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	26-01-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-02-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-02-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-03-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-07-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-08-2023
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

ID: 27635
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2020-002143-27-NL
CCMO	NL73950.100.20
OMON	NL-OMON27635

Study results

Date completed: 16-07-2024

Actual enrolment: 200

Summary results
Trial ended prematurely