Spinal morphine in patients with hip fractures to reduce delirium

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We hypothesize that the use of intrathecal morphine reduces postoperative pain and opioid consumption, which in turn will reduce the incidence of delirium.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27635

Bron
NTR

Verkorte titel
SALMON-MIND

Aandoening

Proximal femur fracture, delirium

Ondersteuning

Primaire sponsor: Maasstad Hospital Rotterdam
Overige ondersteuning: Wetenschapsbureau, Maasstad Hospital, Rotterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The incidence of postoperative delirium during hospital admission, defined according to the DSM-5 criteria

Toelichting onderzoek

Achtergrond van het onderzoek

Delirium complicates surgical treatment for proximal femur fractures in 20-50% of the patients. Many modifiable and non-modifiable risk factors are identified. Two modifiable risk factors are opioid consumption and pain, both of which are reduced with the use of intrathecal morphine. Therefore, a randomized controlled trial is designed to investigate if the addition of intrathecal morphine to spinal anesthesia reduces the incidence of delirium after surgical treatment for proximal femur fractures.

Doel van het onderzoek

We hypothesize that the use of intrathecal morphine reduces postoperative pain and opioid consumption, which in turn will reduce the incidence of delirium.

Onderzoeksopzet

Day of admission:
- Baseline characteristics (such as pre-existing cognitive impairment and serum Neurofilament Light concentration (n=80))

Anesthesia and surgery
- Time to surgery, duration of surgery, type of surgery, estimated bloodloss
- Use of sedation during surgery, conversion to general anesthesia.

Post-operative day 1:
- QoR-15
- Pruritus severity score
- Ondansetron consumption

Post-operative day 2:
- Neurofilament light serum concentration (in a subset of the patients (n=80)).
- Ondansetron consumption

During hospital admission:
- The incidence of delirium, as measured with DSM-5 criteria
- Post-operative opioid consumption
- Time to mobilization after surgery
- Occurence of complications
- Time to fit-for-discharge
- Length of hospital stay.

During the first 5 postoperative days:
- The mean DOSS-scores
- The mean pain-scores

After discharge:
- Discharge facility
- 30 day-mortality

Onderzoeksproduct en/of interventie

Both arms will receive the same preoperative analgesic management, consisting of paracetamol, metamizol (if no contra-indications), a preoperative regional nerve block as soon as possible and opioids if necessary.
Patients will be randomized for the intervention group (receiving 10 mg bupivacaine + 100 mcg morphine in 4 ml) and the control group (receiving 10 mg bupivacaine in 4 ml) for spinal anesthesia. Postoperative analgesic management consists of paracetamol, metamizol (if no contra-indications) and opioids if necessary for both arms.

Contactpersonen

Publiek

Rijnstate Ziekenhuis
Mark Koning

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Femur fracture
- Scheduled for surgery
- Spinal anesthesia

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Contraindications for spinal anesthesia:
o Patients' refusal
o Coagulation disorders (clopidogrel, INR>1.8, anticoagulation with nadroparine (>100 aXa-IE/kg), 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).
o Aortic Valve Stenosis of AVA < 1.0 cm2
o Lumbar malformations (local inflammation, lumbar osteosynthesis material, meningocele, tethered cord)
- Inability to retrieve cerebrospinal fluid by lumbar puncture.
- Contra-indications for intrathecal morphine:
o Chronic opioid or benzodiazepine use (>1 month daily use).
- Allergies to amide-type local anesthetics and morphine.
- Patients who are incapable of making decisions regarding anesthesia and no legal representative is available.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2022
Aantal proefpersonen:	364
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
Will be shared upon reasonable request.

Ethische beoordeling

Positief advies

Datum:	15-03-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54044
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9390
CCMO	NL73950.100.20
OMON	NL-OMON54044

Resultaten