DEPTHip Study: Delirium in Elderly Patients with Trauma of the Hip

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A continuous Fascia Iliaca Compartment Block (FICB) initiated in the Emergency Department and continued throughout the complete hospital admission employing catheter technique will decrease the incidence of delirium in elderly patients with hip...

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

Samenvatting

ID

NL-OMON23223

Bron
Nationaal Trial Register

Verkorte titel
DEPTHip Study (Delirium in Elderly Patients with Trauma of the Hip)

Aandoening

hip fractures - heupfracturen
nerve block - zenuwblokkade
anesthesia - anesthesie
analgesia - analgesie
elderly - ouderen

Ondersteuning

Primaire sponsor: Academisch Medisch Centrum
Meibergdreef 9
1105 AZ
Amsterdam
Overige ondersteuning: ZonMW (projectnr 843001607)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Occurrence of delirium

Toelichting onderzoek

Achtergrond van het onderzoek

BACKGROUND
Hip fractures occur frequently and are usually very painful. Pain itself is an indicator for increased risk of complications. A
complication is delirium, occurring in up to 25% of all elderly patients with hip fractures. For a large proportion, triggers for development of delirium reaches back to the preoperative phase, where polypharmacy (including opioid use) and inadequately treated pain are major risk factors. Delirium is associated with negative health consequences, increased hospital stay, falls, higher mortality, decreased physical
and cognitive function, re-hospitalization, increased risk of dementia and increased societal costs. Therefore, pain should be optimally treated as soon as possible, however the elderly patient poses a challenge in good pain treatment, because of physiological age-related changes, different drug effects, distribution, metabolism and elimination. Opioids frequently lead to respiratory depression, hypotension, nausea/vomiting and sedation in this vulnerable patient group. As a consequence, these drugs are often under dosed and pain treated insufficiently. Besides, drugs as opioids and NSAIDs have been associated with an increased delirium risk.
A nerve block could alleviate these clinical issues. An example of a nerve block frequently utilized in the Emergency Department (ED) is a Fascia Iliaca Compartment Block (FICB), in which local anesthetics are injected underneath the pelvic iliac fascia in order to block femoral, obturator and lateral
cutaneous nerves to provide anesthesia of hip, thigh and knee. Case-series and historically controlled cohort studies show a single-shot FICB is a rapid, safe and easy procedure providing excellent analgesia, decreased opioid need and little risk of complications. Delirium as outcome was reported in one RCT; a decreased delirium incidence after using repetitive, blind, single-shot FICBs (not in the acute setting) with pethidine (deliriogenic properties) as comparison. In order to prevent the need for repetitive insertions, leaving
a catheter would create a route in order to provide continuous analgesia with local anesthetics. Two case series describe this continuous FICB in hip fractures and reported good pain control and decreased length of hospital stay without any infectious complications. No comparison studies have
been done with a continuous FICB.

The objective of the current study is to investigate whether the use of a continuous FICB, started early (in the ED) and continued throughout the complete clinical course of a hip fracture, will decrease occurrence of delirium in elderly patients with hip fractures.

METHODS
This study is designed as a prospective, open, multi-center, randomized interventional trial. Patients will be allocated to continuous FICB or care as usual (according to national guidelines) in a 1:1 ratio and followed up until three months after hospital discharge.

SAMPLE SIZE AND DATA ANALYSIS
The primary outcome (occurence of delirium)
is expected to be distributed normally. Although evidence to prevent delirium is scarce, an absolute reduction of 13% incidence has been reported previously after an intervention. The estimated delirium incidence according to literature
is 25%. The hypothesis is that by using a continuous FICB administered very early in the clinical course in the ED, the incidence can be decreased from 25 to 12%. We will
test superiority of the FICB versus usual care with the Chi Square Test. We will use a significance level of 0.05 and 80% power to detect a clinically relevant between group difference of 13% decrease in incidence. For this analysis, each group will have 154 patients. When accounting for 10% loss to follow-up after three months, a total study population of 340 will be needed. The primary analysis will be based on the intention to treat principle. Per protocol analysis will be performed to check robustness of results. Baseline characteristics will be presented using descriptive statistics. Ordinal data will be analysed using Chi Square Test or Fisher exact test. Continuous data will be assessed by a Student's t-test if normally distributed or Mann Whitney U test if otherwise. Missing data will be corrected by multiple imputation. An economic evaluation will be performed focusing on possible gained benefits of pain management with a continuous FICB compared to care as usual and the related health care costs. The economic evaluation will be performed from a societal perspective with a time horizon of three months and capturing the value of all resources utilized. The economic evaluation will be set up as a Cost-Effectiveness Analysis (CEA). Besides a CEA, a Budget Impact Analysis (BIA) will be performed according to the ISPOR Task
Force principles.

Doel van het onderzoek

A continuous Fascia Iliaca Compartment Block (FICB) initiated in the Emergency Department and continued throughout the complete hospital admission employing catheter technique will decrease the incidence of delirium in elderly patients with hip fractures compared to traditional care with systemic opioids.

Onderzoeksopzet

Three phases:

Phase 1: pain management in the Emergency Department until admission in the hospital

Phase 2: hospital admission; divided in pre-preoperative and post-operative phase)

Phase 3: after hospital discharge until three months after discharge

Onderzoeksproduct en/of interventie

Patients are randomized on a 1:1 ratio to one of the following:

1. Continuous FICB with bupivacaine

With ultrasound guidance, a FICB will be administered and a catheter left in the compartment underneath the iliac fascia. This catheter will remain in place until two days after surgery. Initial pain treatment in the Emergency Department will be with 40 mL bupivacaine 0.25%. Thereafter, until removal of the catheter, pain is treated by titrating bupivacaine 0.125% with a daily maximum of 400 mg.

2. Traditional care with systemic analgesia.

Traditional care (usual care) will be on the discretion of the treating physician or hospital protocols and will comprise of systemic opioids such as fentanyl or morphine. Usually, these opioids are combined with several other drugs, such as: paracetamol, NSAIDs (diclofenac or ibuprofen or naproxen) or dipyrone. (Inter)national guidelines advice morphine as first line agent in elderly patients with hip fractures, as longer acting analgesics are usually required.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Adult patients aged ≥ 55 years

2. A radiographically confirmed hip fracture

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Multiple injuries (polytrauma patients)

2. Previous adverse reaction or known allergy to local anaesthetics or opioids or paracetamol

3. Skin infection in proximity of injection site

4. Delirious state at presentation in the ED

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2016
Aantal proefpersonen:	340
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	09-02-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55714
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5632
NTR-old	NTR5747

Register	ID
CCMO	NL54580.018.15
OMON	NL-OMON55714

Resultaten

Samenvatting resultaten
n/a