PENG RCT

Gepubliceerd: 12-09-2019 Laatst bijgewerkt: 13-12-2022

The clinical efficacy of the PENG block is superior to the femoral nerve block

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

Samenvatting

ID

NL-OMON21715

Bron
NTR

Verkorte titel
PENG vs femoral nerve block RCT

Aandoening

Neck of femur fracture

Ondersteuning

Primaire sponsor: NONE
Overige ondersteuning: NONE

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Pain

Toelichting onderzoek

Achtergrond van het onderzoek

A blinded randomized control trial comparing the femoral nerve block and the PENG hip block in neck of femur patients
Hypothesis - What is the scientifically valid research question being asked?

We hypothesise that, in a surgical setting for neck of femur fractures, the PENG (pericapsular nerve group) regional block is more effective in reducing post-operative pain than the current gold standard regional block, which is the femoral nerve block.

Aims - - What do the investigators intend to achieve with this research project?

ü PRIMARY OUTCOME

- Measuring numeric pain score reduction (on Visual Analogue Scale from 0 to 10) with the PENG hip block versus the femoral nerve block

ü SECONDARY OUTCOMES

- Objective 1: measuring opiate consumption (intra-operatively, in recovery and day 0 and day 1 post-operatively on the ward; in morphine equivalents in mg and mcg) in patients enrolled in this study

- Objective 2: determining incidence of delirium in patients who have had the PENG block using the CAM (Confusion Assessment Method) block compared to patients who have had a femoral nerve block

- Objective 3: assessing length of hospital stay in days for both groups of study patients

- Objective 4: recording quadriceps strength using the Oxford muscle strength score (0 to 5) and time to mobilization (in days and hours) post-operatively in patients

- Objective 5: measuring patient satisfaction with the regional technique

- Objective 6: measuring patient anxiety and depression, using a combination of any of:

Psychosocial status: CES-D (depression), PASS-20 (pain anxiety symptom scale), PCS (pain catastrophizing scale), PROMIS Pain Self efficacy Questionnaire (PSE-Q 2), PROMIS Depression, and PROMIS Pain Interference (PI), 24 hour QoR-15 (Quality of Recovery) questionnaire, or BPI (Brief Pain Inventory).

Objectives - How will investigators achieve the aims of the research project?

We propose a study to investigate the effect of the PENG block, compared to the femoral nerve block in a triple-blind randomised controlled trial format.

We aim to achieve this by randomising participants into a two-armed nested, prospective, single-centre cohort study, to receive either the current gold standard regional technique (femoral nerve block) or our study intervention (the PENG block) along with standard of care.

The patient and surgeon will be blinded to the intervention they have received, while the anaesthetist performing the block will know which they are performing. The post-operative pain team, at Flinders known as the Acute Pain Service (APS), will also be blinded. This team routinely follows up all patients who have received a regional block. They will know that the patient has received a regional technique, but not whether it is a femoral nerve or PENG hip block.

The femoral block and PENG block use the same equipment (ultrasound and Sonoplex needle), and the same local anaesthetic solution in the same dose (20mLs of ropivacaine 0.75%).

Doel van het onderzoek

The clinical efficacy of the PENG block is superior to the femoral nerve block

Onderzoeksopzet

Per-op, peri-op, post-op

Onderzoeksproduct en/of interventie

PENG hip block

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

First party consent, neck of femur patients

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Contraindication to regional anaesthesia, dementia, aged under 44 years

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	12-02-2020
Aantal proefpersonen:	60
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	12-09-2019

Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8043
Ander register	METC : NONE yet

Resultaten