

PENG vs placebo 'sham' block RCT

Gepubliceerd: 25-12-2020 Laatste bijgewerkt: 13-12-2022

The pericapsular nerve group (PENG) block is superior to placebo 'sham' blocks in hip arthroplasty surgery in reducing patients pain scores (Numeric Rating Scale of 0 to 10), on the day of surgery

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20932

Bron

Nationaal Trial Register

Verkorte titel

PENG vs placebo RCT

Aandoening

Osteoarthritis, or other indication for hip replacement surgery

Ondersteuning

Primaire sponsor: NONE

Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Pain score on day 0 (3 hours post-operatively). As a visual numeric rating scale from 0 to 10, zero being no pain and 10 being the worst pain imaginable.

This shall be collected as a baseline pre-operatively (maximum on movement), and then

post-operatively in the Recovery (PACU) Unit, and the morning of Day 1 on the ward, All pain scores are maximum for the time frame. These shall be on active movement, as they shall first mobilise with Physiotherapy prior to the collection of pain scores.

Toelichting onderzoek

Achtergrond van het onderzoek

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

We aim to achieve this by randomising participants into a two-armed nested, prospective, multi-centre cohort study, to receive placebo or our study intervention (the PENG block) along with standard of care.

The participant, anaesthetist and surgeon will be blinded to the study medication administered.

The post-operative pain team, at FMC and Noarlunga known as the Acute Pain Service (APS), will also be blinded. This team routinely follows up all participants who have undergone a hip arthroplasty. They will know that the participant has received a regional technique, but not whether it is with ropivacaine or placebo.

This study shall not influence the surgical technique, this is left entirely to the treating surgeon. Standard Local infiltration analgesia is 100ml of 0.1% ropivacaine with adrenaline. Anaesthetic technique is standardised to the following: a spinal anaesthetic unless contraindicated or unable to be performed despite multiple attempts, dose 2.0-2.8mL bupivacaine plain 0.5%. Post operative analgesia is standardised. Intrathecal morphine is standardised as not to be given. IV dexamethasone dose is standardised at 8mg at time of block placement.

The study investigators shall not recruit their own patients, to prevent any possible coercion. If

necessary, the anaesthetists involved in the study shall exchange places with each other to prevent this.

The placebo block and PENG block shall use the same equipment (ultrasound and chlorhexidine skin disinfectant). Randomisation shall occur following consent and participant inclusion.

To this date, no complications have been described resulting from PENG blocks. One editorial report describes a case of temporary quadriceps weakness following the block, but this is not a complication, and occurs invariably with the femoral nerve block, another commonly performed regional technique. We have also been performing the PENG block for hip surgeries

within our department for some time, and have not noted any complications.

Post-operatively, each participant will be visited on the ward by the Acute Pain Service which is

a routine part of their care. In this consultation they will discuss their pain levels, pain medication use, and ability to mobilise since their surgery, all part of the standard questions

asked by this service. As part of this study, a study investigator shall pre-operatively conduct a series of questionnaires, Brief Pain Inventory, QoR-15, PROMIS anxiety, Pain Catastrophising Scale and PROMIS depression. Post-operatively the QoR-15, and the Brief Pain Inventory will be repeated on Day 1 postoperatively between 0800 and 0930. We shall conduct a timed up and go test pre-operatively as well as postoperatively. This is the time it takes for a patient stand up from a standard height armchair, walk 3 metres, walk back

to the chair, and sit back down.

There is no long term follow up in the primary analysis of this study. There is a planned secondary analysis of persistent and chronic pain/opiate use outcomes to follow at the 6 week and 3 month postoperative points.

Doel van het onderzoek

The pericapsular nerve group (PENG) block is superior to placebo 'sham' blocks in hip arthroplasty surgery in reducing patients pain scores (Numeric Rating Scale of 0 to 10), on the day of surgery

Onderzoeksopzet

Pre-operative, day of surgery, day after surgery, day of discharge

Onderzoeksproduct en/of interventie

- 1.) Non invasive skin markings and blunt needle to simulate a 'sham' block (control group) or
- 2.) study intervention which is ropivacaine 0.5% 20mLs as a PENG block according to the technique described by Giron-Arango et al. in 2018

Contactpersonen

Publiek

AMC (Supervised by AMC Professor Ruurd Jaarsma)
D-Yin Lin

0434001819

Wetenschappelijk

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D-Yin Lin

0434001819

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All primary elective hip arthroplasty surgery patients at Flinders Medical Centre and Noarlunga Hospital

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Cognitive impairment, aged under 18, patient refusal, operation scheduled to finish after hours (due to availability of allied health- especially physiotherapy to mobilise), revision surgery

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	28-06-2021
Aantal proefpersonen:	36
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting

N/A

Ethische beoordeling

Niet van toepassing

Soort:

Niet van toepassing

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	NL9147
Ander register	METC FMC : 292.20 SALHN HREC

Resultaten