PENG vs placebo 'sham' block RCT

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20932

Source
Nationaal Trial Register

Brief title
PENG vs placebo RCT

Health condition

Osteoarthritis, or other indication for hip replacement surgery

Sponsors and support

Primary sponsor: NONE
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Pain scores on Day 1 post-operatively, and Day 2 if they are still admitted. Time to discharge, patient reported outcome measures, complications, opiate consumption, quadriceps strength measured using Oxford grading scale, patient satisfaction, TUG test (timed up and go), PROMs. Possibly time to first mobilisation.

There is also a possible secondary analysis of tertiary outcomes to follow at a later date- of chronic pain and opiate use at 3 months post-operatively. This data shall be collected via a phone call or at the orthopaedic follow up appointments at 6 weeks and 3 months.
Persistent or chronic pain is defined as pain self-reported by the patient at 6 weeks (persistent) and 3 months (chronic).
Persistent or chronic opiate use is defined as opiate use self-reported by the patient at 6 weeks (persistent) and 3 months (chronic).
The tertiary outcomes will not be included in a primary analysis.

Study description

Background summary

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% ropivicaine 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 Catastophising 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.

Study objective

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

Study design

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	28-06-2021

Enrollment:	36
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
N/A

Ethics review

Not applicable
Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9147
Other	METC FMC : 292.20 SALHN HREC

Study results