PENG RCT

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21715

Source
Nationaal Trial Register

Brief title
PENG vs femoral nerve block RCT

Health condition

Neck of femur fracture

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Pain

Secondary outcome

Opiate consumption, psychometric testing, patient satisfaction

Study description

Background summary

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%).

Study objective

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

Study design

Per-op, peri-op, post-op

Intervention

PENG hip block

Contacts

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Eligibility criteria

Inclusion criteria

First party consent, neck of femur patients

Exclusion criteria

Contraindication to regional anaesthesia, dementia, aged under 44 years

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-02-2020
Enrollment:	60
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	12-09-2019
Application type:	First submission

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	NL8043
Other	METC : NONE yet

Study results