ISRCTN69106683 https://doi.org/10.1186/ISRCTN69106683

A study to compare the effect of ankle nerve block versus popliteal sciatic nerve block on pain following forefoot surgery

Submission date
31/07/2022

Recruitment status
Stopped

Registration date
08/08/2022

Overall study status
Stopped

Last Edited
12/12/2023

Condition category
Surgery

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Orthopedic surgery on the forefoot (the front part of the foot including the toes and area just before them) is a common treatment for loss of/reduced function, pain, and/or deformity that can result from a number of conditions. Forefoot surgery is usually performed under anesthesia in combination with a nerve block.
In this study, two nerve blocks will be compared for this orthopedic procedure: an ankle block and a popliteal (space behind the knee) block. These are two commonly used anesthetic techniques. The purpose of a nerve block is to temporarily anesthetize the specific nerves responsible for the pain transmission of the relevant part of the body.
The aim of this study is to learn about the duration of the effect of the nerve block, patient satisfaction, and pain scores up to 14 days after the orthopedic procedure. The study team also wants to evaluate the use of extra painkillers and the different causes that can predict a difference in postoperative pain.

Who can participate?
All patients due to undergo orthopedic surgery on their forefoot and aged 18 years or older can participate. Before agreeing to participate in this study, the study team will fully inform patients about the organizational implications of the study as well as its potential risks and benefits. This way they can decide for themselves whether they want to participate in the study.

What does the study involve?
The nerve blocks are performed using ultrasound. No additional tests will be performed during the study, except possibly to test the effect of the local anesthetic. Participants will be asked to keep a diary on pain relief, use of pain medication, and any adverse effects they experience for the first 7 days after the surgery and on the 14th day after the surgery.

What are the possible benefits and risks of participating?
The results obtained will contribute to a better understanding of the use of these nerve blocks, the psychological aspects, and the overall approach to the treatment of study participants and future patients. Participants will not experience any direct benefit during the study. Participants

will receive additional attention and will be closely monitored throughout the study.
All common medication and anesthetic techniques can have side effects. During this study, only existing general anesthetics are used. Consequently, the possible side effects are only associated with their use. After an ankle block and a popliteal block, temporary loss of strength or numbness may occur. There may also be minor pain or a small bruise at the insertion point. These are the most common side effects and they are usually harmless and temporary.
The clinical trial sponsor, ZiekenhuisNetwerk Antwerpen (ZNA) or Hospital Network Antwerp, has taken out insurance for this study. There will be no additional charge on top of the standard cost for this surgical procedure.
The clinical trial sponsor and all persons involved are bound by professional confidentiality. The personal data of participants will be treated completely anonymously. The study has been evaluated by the various research members and independent members and it has been approved by the ZNA Ethics Committee.
In order to participate in this study, participants must agree, for their own safety, that the researcher will notify their general practitioner of their participation in this study. Participants may not participate in another clinical trial simultaneously without notifying the researcher or study personnel. Participation may be refused for justified reasons. It is also very important that participants cooperate and follow the instructions given to them by the study personnel.
Participation in this study is completely voluntary and should never be done under pressure. Participants have the right not to participate in the study. They may also withdraw from the study at any time without having to give any reason, even if they had previously consented.

Where is the study run from?
ZiekenhuisNetwerk Antwerpen (Belgium)

When is the study starting and how long is it expected to run for?
From December 2021 to January 2024

Who is funding the study?
ZiekenhuisNetwerk Antwerpen (Belgium)

Who is the main contact?
Dr J. Berghmans MD PhD
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Contact information

Type(s)
Principal investigator

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Study information

Scientific Title
Ankle nerve block versus popliteal sciatic nerve block in ambulatory surgery after forefoot surgery (PSNSB-ANB-RCT): an RCT and follow-up study

Acronym
PSNSB-ANB-RCT

Study objectives
1. To assess differences between two ultrasound-guided locoregional anesthesia techniques (ankle nerve block and single-shot popliteal sciatic nerve block) after forefoot surgery regarding:
1.1. Postoperative pain intensity levels
1.2. Self-reported effective duration of analgesia
1.3. Participants' satisfaction
1.4. Functional recovery index (FRI)
1.5. Adherence to postoperative pain medication
2. To explain differences in both postoperative pain intensity levels and functional recovery by exploring candidate predictors such as:
2.1. Age
2.2. Gender
2.3. Body mass index (BMI)
2.4. Socio-economic status (SES)
2.5. Charlson Comorbidity Index (CCI)
2.6. Medication Quantification Scale (MQS)
2.7. Expected postoperative pain
2.8. Postoperative pain medication adherence
2.9. Preoperative state anxiety and need for information
2.10. Pain catastrophizing levels
2.11. Hospital Anxiety Depression Scale (HADS)
2.12. General Self-efficacy Scale (GSE)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/05/2022, Medical Ethics Committee Ziekenhuis Netwerk Antwerpen (ZNA) Institutional Review Board (ZNA/OCMW Antwerpen, Lindendreef 1, 2020 Antwerpen Belgium; +32 3 280 34 29; ethische-commissie@zna.be), ref: 5692

Primary study design
Interventional

Study design
Randomized controlled single-blinded trial with an observational cohort follow-up

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Management of pain in patients undergoing forefoot surgery.

Interventions
Patients will receive either an ultrasound-guided ankle block (group A) or an ultrasound-guided popliteal sciatic nerve block with n. saphenous block (group B) combined with standardized anesthesia and postoperative pain management while in hospital and at home.
An external investigator not involved in this trial will prepare sequence generation. By picking a computer-generated envelope (opaque, sealed, and stapled) participants will be assigned randomly to either group A – ankle block or group B – single-shot popliteal sciatic nerve block (+ n. saphenous). The allocation sequence will be concealed from the research nurse and researcher involved in enrolling participants. The sealed randomization envelope will be opened after enrolment and after completing all baseline demographic medical assessments and questionnaires immediately before the intervention.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Pain measured using the Visual Analogue Scale – Pain (VAS-P) between 0 and 7 days postoperatively and at 14 days postoperatively

Key secondary outcome(s)
1. Functional recovery measured using the Functional Recovery Index (FRI) at 7 and 14 days postoperatively
2. Effective duration of analgesia of locoregional block measured using a Visual Analogue Scale – Pain (VAS-P) and noted in the patient's diary on the day of surgery
3. Participants' subjective satisfaction with placement of the regional block measured using a four-point Likert scale on the day of surgery
4. Pain medication adherence at home measured using participant diaries between 0 and 7 days postoperatively
5. Adverse effects including abnormal proprioception, numbness, paraesthesia, neuralgia, or motor weakness measured using participant diaries between 0 and 7 days postoperatively and at 14 days postoperatively

Completion date
01/01/2024

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
1. Scheduled for ambulatory metatarsal osteotomy/forefoot surgery
2. American Society of Anesthesiologist (ASA) physical status I-II
3. Provides written informed consent

4. Good understanding of the Dutch language
5. Aged ≥18 years
6. Without premedication

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Refusal to participate
2. Aged 18 years
3. Known preexisting neuropathies
4. Known impaired cognitive function
5. Systemic glucocorticoid administration
6. Pregnancy
7. Chronic use of opioids
8. Intolerance for local anesthetics and non-steroidal anti-inflammatory drugs (NSAID)
9. Revision surgery

Date of first enrolment
15/08/2022

Date of final enrolment
15/12/2023

Locations

Countries of recruitment
Belgium

Study participating centre
ZiekenhuisNetwerkAntwerpen - ZNA Middelheim
Lindendreef 1
Antwerp
Belgium
2020

Study participating centre
ZiekenhuisNetwerkAntwerpen - ZNA Jan Palfijn
Lange Bremstraat 70
Merksem / Antwerp
Belgium
2170

Sponsor information

Organisation
ZiekenhuisNetwerk Antwerpen

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
ZiekenhuisNetwerk Antwerpen (ZNA)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	01/05/2022	08/08/2022	No	No
Statistical Analysis Plan	version 1.0	01/05/2022	08/08/2022	No	No