The continuous peripheral nerve blockade for lower limb surgery (CAREFREE) trial

Published: 30-03-2021
Last updated: 15-05-2024

We hypothesize that implementation of ambulatory cPNB for postoperative analgesia in lower limb surgery will be non-inferior regarding patient-reported overall benefit of analgesia, when compared to standard care for pain control using sPNB and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nervous system, skull and spine therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON29369

Source
NTR

Brief title
CAREFREE

Condition

- Nervous system, skull and spine therapeutic procedures

Health condition

Postoperative pain

Research involving
Human

Sponsors and support

Primary sponsor: Department of Anesthesiology, Amsterdam UMC, location AMC.

Source(s) of monetary or material Support: First stream

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

Patient-reported overall benefit of analgesia.

Secondary outcome

Healthcare costs, productivity costs, postoperative opioid consumption, length of hospital stay, incidence of CPSP, postoperative pain, quality of recovery, and adverse events.

Study description

Background summary

Rationale: Patients undergoing (orthopedic) surgery are at risk for postoperative acute and chronic pain. Reliance on opioids for pain management has led to growing public health problems due to potential addiction. Additionally, opioids may contribute to chronic postsurgical pain (CPSP). Peripheral nerve blocks (PNBs) are state-of-the-art for postoperative analgesia in extremity surgery. PNBs reduce opioid consumption, shorten hospital length of stay, improve pain control and patient satisfaction, and prevent hospital readmission. However, analgesic properties of single shot peripheral nerve blocks (sPNBs) last no longer than 12 to 24 hours and may induce rebound pain, thereby leading physicians to prescribe opioids. Placement of a perineural catheter (continuous peripheral nerve block, cPNB) assures continuous infusion of local anesthetic, ensuring ongoing analgesia and reducing rebound pain. cPNBs are a regular part of in-hospital analgesic treatment plans, however, outpatient cPNB is not yet common practice due to organizational challenges resulting from financial restraints. Therefore, current standard of practice utilizes multimodal analgesia consisting of sPNB and opioids to expedite recovery and discharge. cPNBs can, however, play a role in perioperative care for lower extremity surgery by facilitating quality of analgesia comparable to in-hospital in an outpatient setting. Furthermore, widespread adoption of cPNB may provide broad public health benefits by limiting opioid requirement. We hypothesize that implementation of ambulatory cPNB for postoperative analgesia in lower limb surgery will be non-inferior regarding patient-reported overall benefit of analgesia, when compared to standard care for pain control using sPNB and systemic opioids. Ambulatory cPNB will be cost-effective, reduce opioid consumption and incidence of CPSP, enhance patient-reported

quality of recovery, improve postoperative pain scores and shorten length of hospital stay. Objective: The main goal of this study is to investigate the effect of postoperative analgesia using a cPNB on patient-reported overall benefit of analgesia, as measured by the Overall Benefit of Analgesic Score (OBAS). It is hypothesized that cPNB is non-inferior when compared to standard therapy for patient-reported overall benefit of analgesia. Secondary objectives are to study the effect on cost-effectiveness, postoperative opioid consumption, length of hospital stay, postoperative pain, quality of recovery, and incidence of CPSP. Study design: Randomized clinical non-inferiority trial. Study population: Patients eighteen years or older, scheduled for elective, non-outpatient lower limb surgery performed by a trauma surgeon or orthopedic surgeon. A total of 42 subjects will be enrolled in this study. Intervention: The proposed intervention in this study constitutes an organizational change. Research subjects randomized to 'fast-track recovery' participate in a novel perioperative treatment pathway. In the intervention group, research subjects receive a cPNB and are discharged as soon as medically reasonable. The control group is treated for postoperative analgesia according to standard care, using a sPNB and systemic opioids. Main study parameters/endpoints: Primary endpoint: patient-reported overall benefit of analgesia. Secondary endpoints: healthcare costs, productivity costs, postoperative opioid consumption, length of hospital stay, incidence of CPSP, postoperative pain, quality of recovery, and adverse events. Nature and extent of the burden and risks associated with participation, benefit and group relatedness: PNBs are a recognized expertise of anesthesiologists and as such cPNB is a common part of in-hospital analgesic treatment plans. However, utilization of outpatient cPNBs is currently limited due to organizational challenges resulting from financial restraints. As such current standard of practice utilizes multimodal analgesia consisting of sPNB and opioids to facilitate recovery and discharge. This study will therefore explore cost-effectiveness as a secondary objective. cPNBs and sPNBs will be performed employing ultrasound guidance, by a selected group of experienced anesthesiologists. Possible burden to research subjects may be hospital readmission due to insufficient analgesia, this applies to both the intervention arm and the control group. Research subjects will be requested to complete questionnaires three days, thirty days and three months after surgery. Benefits include the positive effects that cPNB may have on length of hospital stay, postoperative pain, quality of recovery, and prevention of negative side-effects of opioids.

Study objective

We hypothesize that implementation of ambulatory cPNB for postoperative analgesia in lower limb surgery will be non-inferior regarding patient-reported overall benefit of analgesia, when compared to standard care for pain control using sPNB and systemic opioids. Ambulatory cPNB will be cost-effective, reduce opioid consumption and incidence of CPSP, enhance patient-reported quality of recovery, improve postoperative pain scores and shorten length of hospital stay.

Study design

Research subjects will complete questionnaires, on paper and/or by phone, daily during the first three days, at 30 days, and three months after surgery.

Intervention

The proposed intervention in this study constitutes an organizational change. Research subjects randomized to ‘fast-track recovery’ participate in a novel perioperative treatment pathway. In the intervention group, research subjects receive a cPNB and are discharged as soon as medically reasonable. The control group is treated for postoperative analgesia according to standard care, using a sPNB and systemic opioids.

Contacts

Public
Amsterdam UMC, location AMC
Pascal Smulders

+31 20 566 2533
Scientific
Amsterdam UMC, location AMC
Pascal Smulders

+31 20 566 2533

Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

- Scheduled for elective, inpatient lower limb surgery - Aged eighteen years or older - Willing and able to provide written informed consent - Able to handle cPNB and equipment

Exclusion criteria

- Polytrauma patients - Emergency surgery - Surgery for (bone) infections - Severe renal and/or hepatic insufficiency - Allergy to local anesthetics - (Suspected) pregnancy - Daycare surgery - ASA 4 or higher - Chronic use of opioids (> 3 months)

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2021
Enrollment:	44
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO

Date:	30-03-2021
Application type:	First submission
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389

mecamc@amsterdamumc.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 50914
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9382
Other	METC AMC : METC2020_280
CCMO	NL75386.018.20
OMON	NL-OMON50914

Study results

Results posted:	20-12-2023
Actual enrolment:	44