The *Continuous peripherAl neRve blockadE FoR lowEr limb surgEry* (CAREFREE) trial

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50914

Source
ToetsingOnline

Brief title
The CAREFREE trial

Condition

- Other condition
- Bone and joint therapeutic procedures

Synonym
discomfort, Postoperative pain

Health condition

Pijnbehandeling

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Continuous peripheral nerve block, Regional anesthesia

Outcome measures

Primary outcome

Patient-reported overall benefit of analgesia, as measured by the Overall

Benefit of Analgesic Score (OBAS).

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

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.

Study 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.

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.

Study burden and risks

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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
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 type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-09-2021
Enrollment:	42
Type:	Actual

Ethics review

Approved WMO Date:	25-03-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-07-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29369
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL75386.018.20
OMON	NL-OMON29369