Efficacy of Pectoral Nerve (PECS II) Block for Breast Conserving Surgery: A Prospective Randomized Controlled Trial

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Postoperative NRS pain scores in the breast after BCS are lower in women who receive a preoperative PECS II block than in women who receive a sham block.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast disorders
Study type	Interventional

Summary

ID

NL-OMON28887

Source
Nationaal Trial Register

Brief title
CONPECS II

Condition

- Breast disorders

Health condition

Breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: St. Antonius Hospital
Source(s) of monetary or material Support: N/A

Intervention

Explanation

Outcome measures

Primary outcome

NRS pain scores in the breast after breast conserving surgery

Secondary outcome

- Postoperative NRS pain scores in the axilla. - Intraoperative need of opiates (milligrams). - Postoperative need of opiates or other pain killers (milligrams). - Patient-reported chronic (> 12 weeks) pain (yes/no). - Patient satisfaction, measured by the BREAST-Q BCT. - Postoperative time that women need to be observed in the recovery room (minutes). - Time until women are discharged from the hospital (hours). - Use of additional anti-emetics for PONV (yes/no). - Vomiting (yes/no). - Operating time (minutes). - Complications (wound infection rate, hematoma, abscess, pneumothorax).

Study description

Background summary

Rationale: Acute postoperative pain is a risk factor for the development of persistent or chronic pain after surgery. The pectoral nerve block type II (PECS II block) is an easy to perform, superficial, peripheral nerve block. Previous literature shows that this block is safe to perform with great effect on postoperative pain relief in patients undergoing mastectomy. However, little is known on the effects of the PECS II block in patients undergoing breast conserving surgery (BSC). Objective: To evaluate the analgesic effects of intraoperative PECS-II block in addition to general anaesthesia for breast conserving surgery (compared to a placebo block). Study design: A prospective randomized, double blind placebo-controlled trial. Study population: Women > 18 years old with breast cancer that are scheduled for BCS in the St. Antonius Hospital in the Netherlands. Intervention: In group 1 we will conduct an ultrasound guided PECS II-block with 30 ml levobupivacaine 0.5% with a maximum of 3 ml/kg. Group 2 receives a sham block consisting of 30 ml sodiumchloride (NaCl) 0.9%. Main study parameters/endpoints: Postoperative pain in the breast and the axilla. Secondary endpoints: intraoperative need of opiates, postoperative need of opiates or other analgesics (pain killers), chronic pain, breast-related patient satisfaction, postoperative time spent in the recovery room, hospital admission time, postoperative vomiting and nausea, operating time and wound infection. Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Subjects undergo a procedure which is generally considered safe, since the block is performed ultrasound guided by with trained physicians, away from

the neuraxis branch. We use medication within its registered indication and the dose is within safety margins. The subjects undergo the PECS-II block under general anaesthesia with standard anaesthetic monitoring. They are not exposed to injections while awake. Patients in group 1 might benefit from participation as they might experience less postoperative pain and might need less postoperative analgesics.

Study objective

Postoperative NRS pain scores in the breast after BCS are lower in women who receive a preoperative PECS II block than in women who receive a sham block.

Study design

All patients will be given a study diary. In this personal book, the NRS will be registered at the following times after termination of the surgery: 30 minutes, 1 hour, 2 hours and 4 hours. The NRS is filled in on the form by either the nurse in the recovery room or the nurse in the ward. After 8, 24, 48 hours and 1, 2, 3, 4, 6 and 12 weeks the NRS is filled on the form by the patient herself. Preoperatively and 6 weeks postoperatively, the patients also fill out the following modules of the BREAST-Q BCT in their diary: psychosocial wellbeing, sexual wellbeing, satisfaction with breasts and physical wellbeing. After completing the questions in this diary, patients can send their diary back to the hospital for free with the included envelope. In order to find out whether patients have chronic pain, we will contact patients after 6 months to follow-up on their pain scores with the NRS and the four BREAST-Q BCT questionnaires.

Intervention

PECS II block with levobupivacaine versus sham PECS II block with NaCl

Contacts

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Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria: - Female gender. - Unilateral breast conserving surgery. - Written informed consent according to ICH/GCP and national regulations. - ASA (American Society of Anesthesiologists) Class I-III .

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: - Women < 18 year old. - Bilateral surgery. - Bleeding disorder or coagulopathy. - Chest wall deformity or infection of injection site. - Another (additional) nerve block (such as TPVB or epidural anesthesia). - Oncoplastic breast conserving surgery. - Autologous or implant based breast reconstruction. - Known allergy for levobupivacaine or local anesthetics from the amide group. - Chronic use of analgesics / opiates preoperatively (> 12 weeks). - Previous breast surgery ipsi- or contralateral (except diagnostic biopsies). - Not able to speak or understand the Dutch language fluently. - Palliative surgery. - Metastatic disease. - Pregnancy or breast feeding. - Psychological, neurological, familial, sociological or geographical factors that could potentially hamper compliance with the study protocol. - Other concurrent solid tumor.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-06-2020
Enrollment:	200
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO

Date:	20-01-2020
Application type:	First submission
Review commission:	Medical Research Ethics Committees United (MEC-U) Postbus 2500 3430 EM Nieuwegein 088 320 8784 info@mec-u.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 50121
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8317
Other	MEC-U : MEC-U: R19.087
EudraCT	2019-004039-21
CCMO	NL71759.100.19
OMON	NL-OMON50121

Study results

Summary results
N/A