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

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The aim of this prospective randomized, double blind placebo-controlled trial study is to evaluate the analgesic effects of preoperative PECS-II block in addition to general anaesthesia for breast conserving surgery compared to a placebo block. Our…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Interventional

Summary

ID

NL-OMON50121

Source
ToetsingOnline

Brief title
CONPECSII

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breastcancer, mammacarcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: St. Antonius Onderzoeksfonds (indirect)

Intervention

Keyword: Breast cancer, Breast conserving surgery, Locoregional anesthesia, PECSII-block

Outcome measures

Primary outcome

To assess whether postoperative NRS pain scores in the breast after BCS is lower in women who receive a preoperative PECS II block than in women who receive a sham block.

Secondary outcome

- To assess whether postoperative NRS pain scores in the axilla after BCS is lower in women who receive a preoperative PECS II block than in women who receive a sham block.
- To assess whether the intraoperative need of opiates in women who undergo BCS is lower in women who receive a preoperative PECS II block than in women who receive a sham block.
- To assess whether the postoperative need of opiates or other pain killers after BCS is lower in women who receive a preoperative PECS II block than in women who receive a sham block.
- To assess whether women have less chronic pain (> 12 weeks) from BCS after receiving a preoperative PECS II block than women who receive a sham block.
- To assess whether women are more satisfied after receiving a preoperative PECS II block than women who receive a sham block, measured by the BREAST-Q BCT.
- To assess whether the postoperative time that women need to be observed in the recovery room after BCS is shorter in women who receive a preoperative PECS II block than in women who receive a sham block.

- To assess whether the time until discharge from the hospital after BCS is shorter in women who receive a preoperative PECS II block than in women who receive a sham block.

- To assess whether women experience less postoperative nausea and vomiting (PONV) after BCS when receiving a preoperative PECS II block compared to those who receive a sham block.

- To assess the difference in operating time in women who undergo BCS is no longer in women who receive a preoperative PECS II block than in a random sample of women who did not receive a PECS II block.

- To assess whether women who undergo BCS with a preoperative PECS II block do not have more wound infections or other complications than women in a random sample who did not receive a PECS II block before their breast conserving surgery.

Study description

Background summary

Breast cancer remains the most common cancer in women. Nowadays, the standard of care for early stage breast cancer is breast conserving surgery (BCS, or lumpectomy) and sentinel lymph node biopsy (SLNB), followed by whole-breast radiotherapy. Long-term survival rates are similar with this treatment as radical mastectomy.

With the introduction of better screening programs and more effective treatment modalities, the survival of breast cancer patients has improved substantially over the past decades. Therefore, the focus of breast cancer patients and physicians is slowly expanding to long-term side effects and quality of life.

An important, invalidating long-term complication of breast cancer surgery is chronic pain, compromising approximately two thirds of women who had breast cancer surgery. Besides type of surgery and radiotherapy, acute postoperative

pain is a risk factor for the development of persistent or chronic pain after breast cancer surgery.

Therefore, several regional anesthesia techniques to decrease postoperative and persistent pain after breast surgery have been developed (e.g., thoracic epidural, intercostal nerve or thoracic paravertebral block). However, these blocks can cause serious complications such as intrathecal spread, nerve damage or epidural hematoma. Moreover, not all anesthetic physicians feel comfortable applying these blocks.

The pectoral nerve block type II (PECS II block) is an easy to perform, superficial, peripheral nerve block that is ultrasound-guided, first introduced in 2012. The PECS II block is a modified PECS I block. A local anesthetic is placed between the pectoralis minor and the serratus anterior muscles (blocking the intercostal and intercostobrachial nerves) and subsequently between the pectoralis major and minor muscles (blocking the lateral and medial pectoral nerves). 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 BCS. Kim et al. (2018) were the first to describe the effects of PECS II in BCS patients. They reported a statistically significant reduction in pain intensity and opioid requirements for 24 hours after BCS and SNB, but questioned the clinical relevance of these findings.

Study objective

The aim of this prospective randomized, double blind placebo-controlled trial study is to evaluate the analgesic effects of preoperative PECS-II block in addition to general anaesthesia for breast conserving surgery compared to a placebo block. Our primary objective is to assess if women who receive a preoperative PECS II block have lower average postoperative pain scores in the breast after breast conserving surgery than women who receive a sham block. Secondary we will evaluate the difference in postoperative pain score in the axilla, intraoperative need of opiates, postoperative need of opiates or other pain killers, chronic pain, breast-related patient satisfaction, postoperative time spend in the recovery room, hospital admission time, postoperative nausea, operating time and wound infection.

Study design

Single center. Prospective, randomized, double-blind and placebo-controlled. One arm receives a pre-operative PECS II block prior to breast-conserving surgery and the second arm receives a sham block with NaCl for BCS.

Intervention

One arm receives a pre-operative PECS II block prior to breast-conserving surgery and the second arm receives a sham block with NaCl for BCS.

Study burden and risks

The sham intervention will not lead to physical or mental suffering, because the administration of the sham block is performed in the operating room after induction of general anesthesia. The risks to be taken do not exceed the humanitarian importance of the problem, because the sham block does not contain any harmful substances (NaCl only) and because a PECS block has been used safely. Previous experience and literature prove this. Based on literature from the PECS block procedures, no complications are associated with the PECS block. We believe that the benefits of a PECS II block can be large and multi-dimensional.

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 the registered indication and the dose is within the safety margins. The subjects receive the PECS II block under general anesthesia with standard anesthetic monitoring. We do not expose them to injections while they are awake. Patients in group 1 may benefit from participation because they may experience less postoperative (acute and chronic) pain and may require fewer postoperative painkillers.

The time load on filling out the patient diary is minimal and does not last longer than 10 minutes at a time. Patients do not need to schedule additional outpatient visits for this study.

In view of the above, we believe that the benefits outweigh the potential burden of risk.

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

- 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

- Women above 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:	Parallel
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

Medical products/devices used

Product type:	Medicine
Brand name:	Chirocaine
Generic name:	Levobupivacaine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	20-01-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-01-2020
Application type:	First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-04-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-05-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-12-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-12-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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: 28887
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2019-004039-21-NL
CCMO	NL71759.100.19
Other	NL8317
OMON	NL-OMON28887