Efficacy of Pectoral Nerve (PECS II) Block with Liposomal Bupivacaine versus Levobupivacaine for Patients undergoing a Mastectomy: A Prospective Randomized Controlled Trial.

Published: 21-02-2023
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This study has been transitioned to CTIS with ID 2024-515183-30-00 check the CTIS register for the current data. The aim of this prospective randomized, double blind study is to evaluate the analgesic effects of pre-operative PECS II-block with (...

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

Summary

ID

NL-OMON53831

Source
ToetsingOnline

Brief title
APECSII

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
Breast cancer, mammacarcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: St. Antonius Onderzoeksfonds 2023

Intervention

Keyword: Breast cancer, Liposomal Bupivacaine, Mastectomy, PECSII-block

Outcome measures

Primary outcome

Postoperative (first 72 hours) NRS pain scores

Secondary outcome

- Postoperative painscores in the axilla

- Intraoperative need of opiates

- Postoperatieve need of opiates and other painkillers

- Chronic pain (>12 weeks)

- Satisfaction, measured by BREAST-Q mastectomy

- Time to discharge

- Postoperative nausea and vomiting (PONV)

Study description

Background summary

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 a positive effect on postoperative pain in patients undergoing mastectomy. Currently the maximal duration of action of local anesthesia is limited, causing insufficient pain relief after mastectomy. This means some women start perceiving pain the night of the operation and need opioids as analgesia. Side effects of opioids (i.e. postoperative nausea and vomiting) are an important reason for a prolonged length of stay. Liposomal bupivacaine is supposed to have analgesic effects up to 72 hours, due to

extended release.

Study objective

This study has been transitioned to CTIS with ID 2024-515183-30-00 check the CTIS register for the current data.

The aim of this prospective randomized, double blind study is to evaluate the analgesic effects of pre-operative PECS II-block with (long-acting) liposomal Bupivacaine versus (short-acting) Levobupivacaine for patients undergoing a mastectomy.

Study design

Multicenter.
Prospective, randomized, double-blind.

Intervention

One arm receives a pre-operative PECS II-block with liposomal Bupivacaine prior to mastectomy and the second arm receives a PECS II-block with Levobupivacaine.

Study burden and risks

When participating to this study, patients are asked to fill in a patient diary with pain scores and medication use. We do not expect increased risks. We expect that patients receiving a PECSII block with liposomal Bupivacaine will have less pain after surgery.

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

- Unilateral mastectomy
- Written informed consent
- Asa I-III

Exclusion criteria

- Age <18 jaar
- (Oncoplastic) breast conserving surgery
- Bilateral surgery
- Bleeding disorder or coagulopathy
- Chest wall deformity or infection of injection site
- Another (additional) nerve block (TPVB or epidural anesthesia)
- Autologous or implant based breast reconstruction
- Known allergy for levobupivacaine or local anesthetics from the amide group
- Known allergy or contra-indication for NSAIDs
- Chronic use of opiates preoperatively (>12 weeks)
- Previous breast surgery ipsi- or contralateral less than 5 years prior to planned mastectomy (except diagnostic biospies)
- Not able to speak or understand the Dutch language fluently
- Pregnancy or breast feeding
- Psychological, neurological, familial, sociological or geographical factors that could potentially hamper compliance with the study protocol

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-10-2023
Enrollment:	130
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Bupivacaine Aurobindo
Generic name:	Bupivacaine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Chirocaine
Generic name:	Levobupivacaine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	EXPAREL liposomal
Generic name:	Lipsomal Bupivacaine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	21-02-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-06-2023
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
EU-CTR	CTIS2024-515183-30-00
EudraCT	EUCTR2022-004128-16-NL
CCMO	NL83450.100.23