The effect of erector spinae plane block on postoperative pain and opioid use in patients undergoing breast cancer surgery with sentinel node dissection

Published: 12-04-2017
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The primary objective of this study is to compare analgesic efficacy of paravertebral block (PVB) with erector spinae plane block (ESPB) in patients undergoing BCS. Since post-operative pain is treated with analgesics we will both assess pain scores…

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

Summary

ID

NL-OMON45604

Source
ToetsingOnline

Brief title
ESPB-pilot

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer surgery, modified mastectomy

Research involving
Human

Sponsors and support

Primary sponsor: Bernhoven

Source(s) of monetary or material Support: door eigen ziekenhuis

Intervention

Keyword: - breast cancer surgery, - locoregional anesthesia, - postoperative pain

Outcome measures

Primary outcome

Main study parameter is reduction in NRS pain score and/or opioid use compared

with women undergoing standard care.

Secondary outcome

Secondary outcome measures are time to perform the procedure, patient

discomfort during the procedure, extend of sensory block, patient satisfaction

with post-operative analgesia, incidence of side-effects and complications.

Study description

Background summary

The incidence of breast cancer in women is high and still increasing. Surgically treated breast cancer patients have one of the highest incidences of chronic pain when compared to other cancer related surgery. Chronification of postoperative pain is amongst other factors influenced by severe acute postoperative pain. Locoregional techniques have gained popularity as an adjunct to general anesthesia for breast cancer surgery (BCS), for their ability to reduce acute postoperative pain with minimal side effects.

Study objective

The primary objective of this study is to compare analgesic efficacy of paravertebral block (PVB) with erector spinae plane block (ESPB) in patients undergoing BCS. Since post-operative pain is treated with analgesics we will both assess pain scores and analgesic use in patients.

Study design

This prospective pilot study will follow 10 patients. Data of these patients

will be compared with data from 10 patients receiving the standard care for this surgery, i.e. PVB. No randomization or blinding will take place.

Study burden and risks

ESPB is considered more safe than PVB since the risk of intra-arterial injection, pneumothorax and hypotension are much more lower because of the anatomic position of the injection site and because block can be placed under ultrasound guidance. Patients participating in this study will not be subjected to any additional risks other than the common risks for breast cancer surgery and a combined general anesthesia and locoregional anesthesia technique.

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

- >18 years old
- ASA I-III
- Written informed consent

Exclusion criteria

- Allergy or contra-indication for paracetamol, etoricoxib or oxycodone
- Chronic opioid use
- Known hypersensitivity or contraindication for local anesthetics
- Bleeding or infection at the puncture site
- Contraindications for regional anesthesia
- Any other reason which in the opinion of the investigator makes the patient unsuitable for participation in the study

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-07-2018
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Naropin
Generic name:	ropivacaine

Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	12-04-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-07-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2017-000709-18-NL
CCMO	NL61106.091.17

Study results

Date completed:	01-05-2019
Actual enrolment:	10

Summary results

Trial is onging in other countries