The effect of a paravertebral block on postoperative pain in patients with breast cancer.

Published: 15-04-2013
Last updated: 26-04-2024

We want to investigate wether a para-vertebral block contributes to a reduced postoperative pain and morphine consumption in patients with breast cancer after a unilateral mastectomy or lumpectomy. By doing this investigation we hope to clarify,...

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

Summary

ID

NL-OMON39535

Source
ToetsingOnline

Brief title
Paravertebral block and breast cancer surgery.

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Breast therapeutic procedures

Synonym
breastcancer

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: geen

Intervention

Keyword: breastcancer, pain, paravertebral block

Outcome measures

Primary outcome

• The pain patients will have postoperatively, will be measured by using

NRS-pain rating scores.

Secondary outcome

• Nausea and vomiting, 2 hours after surgery, 1 day after surgery and 2 days

after surgery.

• The total consumption of analgesia postoperatively, that patients will use.

Study description

Background summary

Pain relief after surgery in patients with breast cancer is one of the basic factors that contribute to adequate treatment and rehabilitation of patients. Several studies show that breast surgery can be associated with postoperative pain, nausea, vomiting and, finally, chronic pain.

There are indications that a paravertebral block provides a more adequate pain relief, less nausea and less vomiting after surgery. In addition, the technique of administering a paravertebral block is relatively easy to learn, and has fewer side effects than other techniques.

However, there is still no clear directive on the use of locoregional anesthetic techniques in breast surgery and the role of morphine use postoperatively.

Study objective

We want to investigate wether a para-vertebral block contributes to a reduced postoperative pain and morphine consumption in patients with breast cancer

after a unilateral mastectomy or lumpectomy. By doing this investigation we hope to clarify, wether a paravertebral block technique can help to improve postoperative outcome in patients undergoing breast surgery.

The main question is: Does addition of a paravertebral block to general anesthesia in patients with breast cancer who will undergo an unilateral mastectomy or lumpectomy give decreased postoperative pain and thereby a reduction in consumption of analgesic medication compared with patients who received only perioperative analgesia intravenously?

Secondary:
Does addition of a paravertebral block to general anesthesia in patients with breast cancer who will undergo breast surgery give less nausea and vomiting compared with patients who receive only intravenous perioperative analgesia?

Does addition of a paravertebral block to general anesthesia in patients with breast cancer who will undergo breast surgery give a reduction in chronic pain compared with patients who receive intravenous perioperative analgesia?

Study design

All patients will undergo surgery in the elective setting. Before randomization, all patients will be stratified by the type of operation: Unilateral mastectomy or lumpetctomy with or without SNB and / or unilateral mastectomy with or without axillary node dissection. The patients will be randomized into two equal groups using sealed envelopes.

Preoperatively, all patients will receive 1000 mg Paracetamol. Both groups will receive general anesthesia using Ultiva (Ultiva, GlaxoSmithKline BV, RVG number 20601) and Propofol (Propofol-Lipuro, B. Braun Melsungen AG, RVG number: 24720)

Patients in group 1 will receive on the holding a paravertebral block. There will be 15-20ml Ropivacaine (Ropivacaine HCl Fresenius Kabi, RVG number 104941) 0.75% given via the paravertebral catheter.
Post-operatively patients will get 3-6ml/hour Ropivacaine via the paravertebral block. The catheter will be removed +/- 48 hours post-operatively.

Patients in group 2 will only receive general anesthesia using Ultiva and Propofol and won't get a paravertebral block.

All patients will get analgesic basic medication post-operatively, 4dd 1000mg Paracetamol and Naproxen 500mg 2dd given. In addition, both groups receive after the operation a PCA pump with Dipidolor. Dipidolor 1.5 mg per bolus will be given with a lockout of 6 minutes. Alternative opioids can be given in patients who don't tolerate Dipidolor.

Intervention

Paravertebral block, There will be 15-20ml Ropivacaine (Ropivacaine HCl Fresenius Kabi, RVG number 104941) 0.75% given via the paravertebral catheter.

Study burden and risks

There is a risk for a pneumothorax and epidural spread. However this risk is 0.5%. (Schnabel e.a. Efficacy and safety of paravertebral blocks in breast surgery: a meta-analysis of randomized controlled trials.Br J Anaesth. 2010) The paravertebral techniques that will be used in this study, have already been practised frequently in the Jeroen Bosch Ziekenhuis. A paravertebal block has been offered to patiënts. Therefore, there is a slight additional load and/or risk.

Contacts

Public
Jeroen Bosch Ziekenhuis

Henri Dunantstraat 1
's Hertogenbosch 5223GZ
NL
Scientific
Jeroen Bosch Ziekenhuis

Henri Dunantstraat 1
's Hertogenbosch 5223GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients between 18-75 year with primary breast cancer Tumor Stage 1-3, Nodes 0-2 who are scheduled for unilateral mastectomy or lumpectomy, with or without SLN and/or axillary node dissection.

Exclusion criteria

Previous breast surgery on same breast.
American Society of Anesthesiologiscts Physical Status 4 or higher
Contraindication to paravertebral anesthesia and analgesia including infection of the punction area, abnormal anatomy and coagulopathy.
Any contraindication to propofol, sevoflurane, fentanyl, or morphine or dipidolor.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2013
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	15-04-2013
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	02-02-2015
Application type:	Amendment
Review commission:	METOPP: Medisch Ethische Toetsing Onderzoek bij Patienten en Proefpersonen (Tilburg)

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
CCMO	NL41537.028.12