Ultrasound-guided erector spinae plane block versus paravertebral block in breast cancer patients undergoing mastectomy with immediate reconstruction - a non-inferiority trial.

Published: 04-05-2021
Last updated: 18-11-2024

The objective of this study is to assess the non-inferiority of analgesic efficacy of ESP vs PVB for patients undergoing unilateral mastectomy followed by immediate reconstruction.

Ethical review	Approved WMO
Status	Completed
Health condition type	Breast therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON50985

Source
ToetsingOnline

Brief title
The ESP study

Condition

- Breast therapeutic procedures

Synonym
Breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: NKI-AVL

Intervention

Keyword: ESP, Mastectomy, Paravertebral block, Ultrasound-guided erector spinae plane block

Outcome measures

Primary outcome

- Mean difference of highest numerical rating score (NRS - a linear 11 point

scale for self-reported pain) during admission in the recovery room

- Difference in the ratio of the means of cumulative opioid dose (administered

during admission in the recovery room)

Secondary outcome

- Success rate as defined by satisfactory spread of local anaesthetic agents on

ultrasound

- Ease of procedure (self-reported by anaesthetist on scale of 1-5)

- Total opioid dose administered on day 0 and on day 1 (iv, subcutaneous or

oral - converted to morphine equivalent dose (MEQ)

- Highest pain score on day 0 and 1

- Time to readiness for discharge from the recovery room

- Complications of block (such as block failure, epidural hematoma, hemo- or

pneumothorax and symptoms of toxicity of local anesthetics)

- Patient satisfaction on a scale of 0 (extremely unsatisfied) tot 10

(extremely satisfied)

Study description

Background summary

In breast cancer treatment, surgery plays a central role in combination with chemotherapy, radiation and immunotherapy. Surgery may vary from conservative breast sparing interventions to large radical mastectomies with axillary lymph node dissection that require reconstructive (prosthetic) surgery. In many instances, reconstruction is not performed immediately, but immediate reconstruction is possible and offers many advantages to patients.
The Antoni van Leeuwenhoek hospital performs a large proportion (77%) of mastectomies with immediate reconstruction in the Netherlands. The combination of mastectomy with immediate reconstruction in one operation offers an extra challenge with regards to pain control. Post-operative pain is often treated with opioids, which has systemic side effects (nausea and vomiting). Opioids also inhibit cell-mediated immunity, which is a principal defense against cancer. Regional anesthetic techniques are often performed to reduce opioid consumption and enhance postoperative recovery.
The current standard for regional anesthesia for breast surgery is the paravertebral block (PVB). This technique has the potential for severe complications such as epidural hematoma, hemo- or pneumothorax. The erector spinae plane block (ESP) was first described in 2016 as a novel regional anesthetic technique for acute and chronic thoracic pain. The site of injection is distant from the pleura, major blood vessels, and spinal cord; hence, the ESP block has relatively few contraindications and has therefore been suggested as an alternative to PVB when contra-indications, such as a bleeding diathesis, are present.
Multiple studies have shown a decrease in opioid consumption in patients undergoing mastectomy, when ESP was compared to placebo. ESP has also been shown to be non-inferior to PVB for pain relief in patients undergoing thoracotomy. To date, only two studies have compared ESP to PVB for breast surgery, with conflicting results. In this study, we would like to investigate whether ESP can be considered non-inferior to PVB with regards to pain relief and use of opioids

Study objective

The objective of this study is to assess the non-inferiority of analgesic efficacy of ESP vs PVB for patients undergoing unilateral mastectomy followed by immediate reconstruction.

Study design

A prospective, double-blinded, single centre, randomized controlled

non-inferiority trial.

Intervention

Pre-operative ultrasound guided single shot paravertebral block versus ultrasound guided single shot erector spinae plane block.

Study burden and risks

The burden for the patient is comparable to standard care with low risk. All patients receive an injection of subcutaneous local anaesthetics followed by insertion of a needle to perform PVB or ESP while the patient is awake or lightly sedated. The complication risk of the intervention (ESP) is lower than the risk of the standard technique (PVB) for local anaesthetic toxicity, epidural hematoma, hemato- and pneumothorax. The ESP is performed at a greater distance of spinal cord, nerve roots and blood vessels compared to the PVB. ESP has been show to provide analgesia compared to placebo in patients undergoing breast surgery. It has been shown to be a safe block that is easy to learn and requires less time to perform.(1) The patients are under general anaesthesia during surgery under constant monitoring of vital parameters. They receive patient-controlled opioid analgesia as rescue medication if needed and are monitored by ward nurses and a physician assistant that has specialised in pain medicine following discharge from the recovery room.

Contacts

Public
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066CX
NL
Scientific
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Adult patients (18 years of age or older)
- ASA I-III
- Patients scheduled for elective unilateral mastectomy followed by direct reconstruction
- Ability to give written and oral informed consent

Exclusion criteria

- Patient refusal
- Non-elective surgery
- Any contraindication to paravertebral block (including bleeding diathesis, coagulopathy, severe pulmonary disease)
- Allergy to amide-linked local anaesthetics
- Cardiac conductivity disorders (e:g: 2nd and 3rd AV-block)
- Severe spinal malformations or history of extensive spine surgery
- A history of spinal cord injury
- Known psychiatric disorder
- Chronic pain patients or patients already using opioids pre-operatively
- Infection of the skin at the site of needle puncture area
- Inability to give oral and written informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	30-09-2021
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	04-05-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	02-05-2022
Application type:	Amendment
Review commission:	METC NedMec

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: 26286
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL75733.031.20
OMON	NL-OMON26286