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Comparison of three nerve block techniques on postoperative pain and recovery after modified radical mastectomy

Submission date
06/11/2025

Recruitment status
No longer recruiting

Registration date
07/11/2025

Overall study status
Completed

Last Edited
07/11/2025

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
A modified radical mastectomy is a procedure in which the entire breast is removed, including the skin, areola, nipple, and most axillary lymph nodes. It often causes significant postoperative pain that may delay recovery. This study compares three regional anesthesia techniques — erector spinae plane block (ESPB), thoracic paravertebral block (TPVB), and pectoral nerve block (PECS) — to determine which provides better pain relief and improves quality of recovery.

Who can participate?
Adult female patients aged 18–70 years, with ASA physical status I–II, scheduled for unilateral modified radical mastectomy. Patients with obesity, previous breast surgery, coagulation disorders, allergies to study drugs, severe systemic diseases or opioid use were excluded.

What does the study involve?
Participants were randomly allocated to receive ESPB, TPVB, or PECS block before general anesthesia. All patients received the same surgical and anesthetic treatment. Pain scores, morphine use, side effects, and quality of recovery were assessed over 24 hours after surgery.

What are the possible benefits and risks of participating?
Participants may experience improved pain control and comfort. Risks are minimal and limited to those associated with standard regional anesthesia techniques (e.g., bleeding, infection, block failure).

Where is the study run from?
Afyonkarahisar Health Sciences University (Türkiye)

When is the study starting and how long is it expected to run for?
February 2021 to March 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Bilal Atilla Bezen, drbilalatilla@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A randomized controlled trial comparing the effects of erector spinae plane block, thoracic paravertebral block, and pectoral nerve block on postoperative analgesia and Quality of Recovery-15 in patients undergoing modified radical mastectomy

Study objectives
Primary Objective:
To compare the effects of erector spinae plane block (ESPB), thoracic paravertebral block (TPVB), and pectoral nerve block (PECS) on postoperative opioid consumption in patients undergoing modified radical mastectomy.

Secondary Objectives:
To compare time to first analgesic request, QoR-15 scores, pain scores, side effects, and patient satisfaction between the three block techniques.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 30/04/2021, Afyonkarahisar Health Sciences University Clinical Research Ethics Committee (Afyonkarahisar Sağlık Bilimleri Üniversitesi | TIP FAKÜLTESİ | Zafer Sağlık Külliyesi A Blok, Dörtyol Mah. 2078 Sok. No:3, Afyonkarahisar, 03030, Türkiye; +90 (0)272 246 33 01; info@afsu.edu.tr), ref: 335

Study design
Single-centre prospective randomized controlled single-blind clinical trial with parallel group assignment

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Breast cancer

Interventions
A computer-generated randomization sequence was used for participant allocation into three intervention groups (ESPB, TPVB, and PECS), and group assignments were concealed using sealed opaque envelopes. All groups received the same standardized general anesthesia protocol, serving as the control framework for comparison between the different regional techniques. After the operation, the patient's medical follow-up and treatment were performed by a researcher blinded to the study.

Intervention Type
Other

Primary outcome(s)
Total morphine consumption (mg) measured using the patient-controlled analgesia (PCA) device at 24 hours postoperatively

Key secondary outcome(s))
1. Time to first morphine request, recorded from arrival in recovery until the first PCA morphine dose request (minutes)
2. Postoperative pain intensity, measured using the Visual Analog Scale (VAS) at 0, 1, 3, 6, 12, and 24 hours at rest and during movement
3. Quality of Recovery, assessed using the Quality of Recovery-15 (QoR-15) questionnaire at 24 hours postoperatively
4. Incidence of rescue fentanyl administration, based on VAS ≥4, within the first 24 hours
5. Incidence of postoperative nausea and vomiting (PONV) within 24 hours, recorded as present

or absent
6. Patient satisfaction with analgesia, assessed at 24 hours using a 5-point Likert scale

Completion date
23/03/2023

Eligibility

Key inclusion criteria
1. American Society of Anesthesiologists (ASA) physical status I–II
2. Scheduled for unilateral modified radical mastectomy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
70 years

Sex
Female

Total final enrolment
90

Key exclusion criteria
1. Obesity
2. Previous breast surgery
3. Bleeding disorders
4. Allergies to study drugs
5. Anticoagulant or chronic analgesic use
6. Severe cardiac, hepatic, or renal disease

Date of first enrolment
15/05/2021

Date of final enrolment
22/03/2023

Locations

Countries of recruitment

Türkiye

Study participating centre
Afyonkarahisar Health Sciences University
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Sponsor information

Organisation
Afyonkarahisar Health Sciences University (Afyonkarahisar Sağlık Bilimleri Üniversitesi)

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
Due to institutional and national legal restrictions, individual participant data cannot be shared.

IPD sharing plan summary
Not expected to be made available