Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of Ultrasound-Guided Bilateral Erector Spinae Plane (ESP) Block Combined with Tumescent Anesthesia Versus Tumescent Anesthesia Alone for Postoperative Analgesia in Mammoplasty Candidates: A Clinical Trial

Protocol summary

Study aim

Investigating the Effect of Ultrasound-Guided Bilateral Erector Spinae Plane Block on Quality of Recovery in Candidates for Reduction Mammoplasty

Design

A randomized, double-blind, parallel-group, controlled clinical trial on 100 patients(50 patients in each group).Randomization was performed using a random number table generated by the org.Randomizer software with a 1:1 allocation ratio.

Settings and conduct

This randomized, double-blind clinical trial is being conducted on women who undergo reduction mammoplasty at Shohada Ashayer hospital. Patients will be randomly assigned (with concealment via opaque, sealed envelopes) to two groups: intervention group and control group.In this study, surgeon and outcome expectations are independent of the groupings.

Participants/Inclusion and exclusion criteria

Inclusion Criteria:Women aged 18 to 65 years, candidates for elective reduction mammoplasty, with a Body Mass Index of 18 to 35, who have provided informed consent. Exclusion Criteria:Inability to understand the questionnaire, inability to use Patient-Controlled Analgesia, allergy to local anesthetics (amides), coagulation disorders, history of breast or thoracic spine surgery,substance abuse, and severe psychiatric disorders.

Intervention groups

Both groups receive general anesthesia and tumescent solution. The intervention group receives an ultrasound-guided bilateral ESP block (60 ml of 0.25% levobupivacaine at T5), while the control group receives a sham subcutaneous saline injection.

Main outcome variables

Primary Outcome: Quality of recovery 24 hours post-surgery, assessed using the QoR-15 questionnaire. Secondary Outcomes: Total opioid consumption (MME) in the first 24 hours; pain severity (NRS) from 30 minutes to 24 hours post-operatively; time to first analgesic request; incidence of post-operative nausea and vomiting (PONV); duration of hospital stay; and adverse events.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230410057871N12**
Registration date: **2026-06-17, 1405/03/27**
Registration timing: **prospective**

Last update: **2026-06-17, 1405/03/27**
Update count: **0**

Registration date

2026-06-17, 1405/03/27

Registrant information

Name

Arian Karimi Rouzbahani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-06-21, 1405/03/31

Expected recruitment end date

2026-08-22, 1405/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Ultrasound-Guided Bilateral Erector Spinae Plane (ESP) Block Combined with Tumescent Anesthesia Versus Tumescent Anesthesia Alone for Postoperative Analgesia in Mammoplasty Candidates: A Clinical Trial

Public title

Evaluating the Effect of ESP Block on Postoperative Pain in Mammoplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Female patients aged 18 to 65 years Candidates for elective reduction mammoplasty Body Mass Index (BMI) between 18 and 35 kg/m² American Society of Anesthesiologists (ASA) physical status class I or II

Exclusion criteria:

History of known allergy to local anesthetics (amides) Infection at the block injection site Drug or alcohol abuse Severe psychiatric disorders

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Computer-generated randomization using an online random number generator (Randomizer.org) with a 1:1 allocation ratio. To ensure allocation concealment, the randomization sequence will be generated by a statistician and concealed in sequentially numbered, opaque, sealed envelopes. The envelopes will be opened by the anesthesiologist only after the induction of general anesthesia.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomized, Double-blind trial. The patient, the operating surgeon, and the outcome assessor (evaluating pain and quality of recovery) will be completely blinded to the group allocations. To preserve patient blinding, the block intervention is strictly performed after the induction of general anesthesia.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Lorestan University of Medical Sciences

Street address

Moallem Street, Shahid Anushiravan Rezaei Square

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Approval date

2022-04-13, 1401/01/24

Ethics committee reference number

IR.LUMS.REC.1404.369

Health conditions studied

1

Description of health condition studied

Macromastia (Breast Hypertrophy) / Candidates for Reduction Mammoplasty

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Quality of Recovery (QoR) score

Timepoint

24 hours postoperatively

Method of measurement

Measured using the standard 15-item Quality of Recovery (QoR-15) questionnaire

Secondary outcomes

1

Description

Postoperative pain intensity

Timepoint

At 30 minutes, 1, 2, 4, 6, 12, and 24 hours postoperatively

Method of measurement

Measured using the Numeric Rating Scale (NRS - score 0 to 10)

2

Description

Total opioid consumption

Timepoint

During the first 24 hours postoperatively

Method of measurement

Calculated and reported as Morphine Milligram Equivalents (MME)

3

Description

Time to first analgesic request

Timepoint

From the end of surgery until the patient’s first request for analgesia

Method of measurement

Exact time recorded in minutes/hours by the assessor

4

Description

Postoperative nausea and vomiting (PONV)

Timepoint

During the first 24 hours postoperatively

Method of measurement

Clinical assessment and documentation of incidence

5

Description

Length of hospital stay

Timepoint

At the time of patient discharge

Method of measurement

Calculated from admission to discharge in hours/days

6

Description

Adverse effects / Complications

Timepoint

During hospitalization and up to 24 hours postoperatively

Method of measurement

Clinical examination and documentation of any complications (e.g., local anesthetic toxicity, infection, hematoma)

Intervention groups

1

Description

Intervention group:In the intervention group, following the induction of general anesthesia and prior to the commencement of surgery, a bilateral Erector Spinae Plane (ESP) block is performed under sterile conditions. Using an ultrasound machine equipped with a linear probe, the transverse process of the fifth thoracic vertebra (T5) is identified. A 22-gauge echogenic needle is then inserted using an in-plane technique into the fascial plane between the erector spinae muscle and the transverse process. After confirming the correct needle placement by injecting 1 to 2 mL of normal saline, 0.25% levobupivacaine (manufactured by [sina pishgam daroo novin]) is injected. The administered dose is 30 mL on each side (a total of 60 mL). This intervention is performed only once as a single dose prior to the surgery

Category

Treatment - Drugs

2

Description

Control group:In the control group, patients undergo reduction mammoplasty following the induction of standard general anesthesia (identical to the intervention group). To maintain the blinding of the study for both the patient and the outcome assessor, a sham injection (subcutaneous normal saline) is administered instead of a local anesthetic. For this purpose, 0.9% normal saline (manufactured by [shahid ghazi]) is used. The injection volume is 30 mL on each side (a total of 60 mL), administered as a single dose just once prior to the surgical incision. Additionally, similar to the intervention group, a standard tumescent solution is injected into the surgical site by the surgeon. In this group, no injections are performed in the paravertebral area or the Erector Spinae Plane, and patients only receive general anesthesia, a subcutaneous sham injection, and surgical tumescent infiltration

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Ashayer Hospital

Full name of responsible person

Arian Karimi Rouzbahani

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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Khoram-Abad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available