

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of Ultrasound-Guided Bilateral Erector Spinae Plane (ESP) Block Combined with Tumescant Anesthesia Versus Tumescant 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 tumescant 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

Recruitment complete

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 Tumescant Anesthesia Versus Tumescant 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

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Peyman Astaraki

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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

Contact**Name of organization / entity**

Khoram-Abad University of Medical Sciences

Full name of responsible person

Arian Karimi Rouzbahani

Position

Medical Doctor

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Full name of responsible person

Siavash Beiranvand

Position

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Specialist

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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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