Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of efficacy of ultrasound guided pectoral nerve block (PECS II) versus serratus anterior block (SAB) on postoperative pain in breast cancer surgery

Protocol summary

Study aim
Comparison of efficacy of ultrasound guided pectoral nerve block (PECS II) versus serratus anterior block on postoperative pain in breast cancer surgery

Design
Clinical trial with control group, with parallel groups, One-blind, randomized, phase 3 on 300 patients. In order to randomize, the block randomization method will be used.

Settings and conduct
In this study, all patients who are candidates for breast cancer surgery at Rasoul Hospital in Tehran will be enrolled. Patients will be randomly divided into 2 groups based on size 4 blocks. The sample size for each study group is 40 people. A total of 80 patients will be examined. Patients and information analysts will be blind. The amount of pain; Patient satisfaction and analgesia; Patients will be asked 6, 12, and 24 hours after surgery, and the dose of general anesthesia will be measured and compared between the two groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients over 18 years; Candidate for lumpectomy or partial mastectomy; Perform surgery under general anesthesia. Exclusion criteria: Prohibition of any nerve block; History of bleeding disease; Drug allergy; History of liver or kidney failure; Obesity (BMI above 35); Pregnancy or lactation; History of drugs addiction; History of neurological diseases; Infection of block; History of breast surgery; patients over 60 years.

Intervention groups
Intervention group 1: Type II pectoral nerve block.
Intervention group 2: Anterior Ceratus block under ultrasound guide.

Main outcome variables
The amount of pain; Patient satisfaction; Patient analgesia; Total dose of anesthesia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211215053419N1**
Registration date: **2022-02-26, 1400/12/07**
Registration timing: **prospective**

Last update: **2022-02-26, 1400/12/07**
Update count: **0**

Registration date
2022-02-26, 1400/12/07

Registrant information

Name
Parinaz Morovati sharif abadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4608 8077

Email address
parinazmorovati43589@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-06, 1400/12/15

Expected recruitment end date
2022-07-23, 1401/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of efficacy of ultrasound guided pectoral nerve block (PECS II) versus serratus anterior block (SAB) on postoperative pain in breast cancer surgery

Public title
Efficacy of ultrasound guided pectoral nerve block versus serratus anterior block on pain

Purpose
Other

Inclusion/Exclusion criteria

Inclusion criteria:
Patients over 18 years old Candidate for lumpectomy or partial mastectomy Perform surgery under general anesthesia

Exclusion criteria:
Prohibition of any nerve block History of bleeding disease Drug allergy History of liver or kidney failure Obesity Pregnancy or lactation History of drugs addiction History of neurological diseases Infection of the site of the block History of breast surgery Patients over 60 years old

Age
From **18 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly assigned to two groups by using a random number table. In order to randomize, a random block method will be used. For this purpose, we formed blocks of size 4. In each block, 2 individuals will be in intervention group 1 and 2 will be in intervention group 2. A total of 20 blocks will be considered for the study. Random Block Quadruple All possible blocks are arranged as follows: block 1: ABAB block 2: AABB block 3: ABBA block 4: BBAA block 5: BABA block 6: BAAB We need 20 blocks to select 80 people. We randomly select these blocks from 1 to 6. Using the software, we choose a random number between the numbers 1 to 6. For example, if the number 6 is selected as the first block and the number 2 as the second block, the people who enter the study will be given BAABAABB, respectively. Finally, group A receives control intervention and group B receives treatment intervention.

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients will be unaware and blind to the type of treatment. Similar envelopes were used for hiding, without the name tag of the block method and only with the code. Patients will be aware that they will be randomly assigned to one of two treatment groups, but will not know which treatment will be offered in that group. Patients will be placed in one of two groups using a table of random numbers. The data collector and analyst will collect and analyze the information based on groups 1 and 2, and will not be aware of the type of treatment provided in the groups and will be kept blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Iran University of Medical Sciences, Hemmat Highway

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2021-12-04, 1400/09/13

Ethics committee reference number
IR.IUMS.FMD.REC.1400.528

Health conditions studied

1

Description of health condition studied
Breast cancer

ICD-10 code
C50

ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
The amount of pain

Timepoint
6, 12 and 24 hours after surgery

Method of measurement
Based on Numerical Rating Scale

2

Description
Patient satisfaction

Timepoint
6, 12 and 24 hours after surgery
Method of measurement
Based on Likert scale

3

Description
Patient analgesia
Timepoint
6, 12 and 24 hours after surgery
Method of measurement
Ramsay sedation scale

4

Description
Total dose of anesthesia
Timepoint
After surgery
Method of measurement
Based on patient records

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Type II pectoral nerve block. The block will be performed after general anesthesia. The purpose of this block is to penetrate the two fascia compartments by dividing the dose of local anesthesia between the pectoral nerve in the pectoralis minor muscle. This block is performed by placing the patient supine and placing the surgical side arm in a 90 degree position. The linear transducer is located on the outer side of the midline of the clavicle at the level of the third rib, and in the first injection approximately 0.2 ml per kg of ropivacine is injected 0.25 between the pectoralis major and minor muscles, for lateral and medial pectoral nerve blocks. The transducer is rotated slightly to create a path for the needle from the top and inside to the side. While the second injection was in the axillary anterior line and at the level of the fourth gear with 0.2 ml per kg of ropivacine 0.25 between the pectoralis minor and the anterior ceratus muscle, using a linear transducer with a depth of 1 to 4 cm and a needle. Local block is performed. The injection depth is usually 1 to 3 cm for the first injection and 3 to 6 cm for the second injection.
Category
Treatment - Surgery

2

Description
Intervention group 2:Anterior Ceratus block under ultrasound guide. The block will be performed after general anesthesia under an ultrasound guide with a portable ultrasound device. In this block the linear transducer is located on the midaxillary line and at the level of the fifth gear. A block needle is inserted from the outer edge of the transducer and moves forward until the tip of the needle reaches each plate between the thoracic fascia on the ultrasound image. Following the detection of ultrasound signs, a linear transducer with a depth of 1 to 4 cm and a local block needle can be performed and an injection of 0.4 ml per kg of ropivacaine 0.25 block will be performed. Device model: Portable Sono Site, HFL50X/15-6 MHz Trancducer، Made in USA.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Rasoul Akram hospital
Full name of responsible person
Parinaz Morovati Sharif Abadi
Street address
Hazrate Rasool hospital, Niyayesh street, Sattarkhan
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6435 2190
Email
hrmc@iums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Hossein Keyvani
Street address
Iran University of Medical Sciences, Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 2503
Email
research@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Parinaz Morovati Sharif Abadi
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Hazrate Rasool hospital, Niyayesh street, Sattarkhan
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 4608 8077
Email
parinazmorovati43589@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Parinaz Morovati Sharif Abadi
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Hazrate Rasool hospital, Niyayesh street, Sattarkhan
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 4608 8077
Email
parinazmorovati43589@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Parinaz Morovati Sharif Abadi
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Hazrate Rasool hospital, Niyayesh street, Sattarkhan
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 4608 8077
Email
parinazmorovati43589@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty