Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of pectoral nerve block Vs field block in transsexual patients undergoing breast reconstruction surgery

Protocol summary

Study aim
Comparison of pectoral nerve block Vs field block in transsexual patients undergoing breast reconstruction surgery

Design
This study is a single-blind randomized clinical trial in which the number of patients is determined according to the sample size formula and using a simple randomization method, which uses a random number table for each patient. The code is given and patients are randomly assigned to two treatment groups, with random code selection.The sample size in this study is 50 patients.

Settings and conduct
After standard monitoring, patients are anesthetized with intravenous drugs. After the surgery, the patients are placed under a nerve block in one of two ways. In the pectoral nerve block group, after the surgery, the ultrasound probe is placed on the Infraclavicular area and moved to the artery and the axillary vein above the first rib to the outside just above the junction of the pectoralis major and minor muscles at the window location. The syringe is then inserted between the two muscles and 10 ml of ropivacaine is injected to block the internal pectoral nerve as well as the external pectoral nerve . In the second group, the nerve block is performed by a surgeon.This study is being performed at Firoozgar Hospital in Tehran.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Transsexual patients with ASA I-II anesthesia score and candidate for mastectomy
Exclusion criteria: Age less than 18 years or older than 50 years, Obesity, History of pregnancy or lactation,

Intervention groups
In this study, transsexual patients undergoing breast reconstruction surgery are divided into two groups : In the first group, the pectoral nerve block II is performed after surgery with an ultrasound machine.In the second group, the intercostal nerve block is performed after surgery.

Main outcome variables
Pain, nausea, vomiting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151107024909N10**
Registration date: **2020-05-19, 1399/02/30**
Registration timing: **prospective**

Last update: **2020-05-19, 1399/02/30**
Update count: **0**

Registration date
2020-05-19, 1399/02/30

Registrant information

Name
Faranak Rokhtabnak

Name of organization / entity
Iran University of Medical Science

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-20, 1399/02/31

Expected recruitment end date
2020-09-19, 1399/06/29

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of pectoral nerve block Vs field block in transsexual patients undergoing breast reconstruction surgery

Public title
Comparison of pectoral nerve block Vs field block in transsexual patients undergoing breast reconstruction surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Transsexual patients with ASA I-II anesthesia score and candidate for mastectomy Age range between 18 and 50 years
Exclusion criteria:
Age less than 18 years or older than 50 years Obesity History of pregnancy or lactation History of allergy to anesthetics History of hemorrhagic disease
Age
From **18 years** old to **50 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
For randomization, a simple randomization method is used, which is done using a table of random numbers.To use the number of random numbers, we first determine the reading path of the table numbers (for example, top, bottom, left or right).Then we assume certain numbers for each group (for example, even numbers for intervention A and odd numbers for intervention B).Then we touch on one of the numbers and move in one of the predetermined directions and record the numbers and assign them to different groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, a person who is responsible for analyzing statistical data is not aware of the treatment process and study groups and the information is provided to that person in groups A and B. This helps the person's personal opinion not to affect the results
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., Next to Milad Tower., Tehran Town
City
Tehran
Province
Tehran
Postal code
1433933111
Approval date
2020-05-11, 1399/02/22
Ethics committee reference number
IR.IUMS.FMD.REC.1399.119

Health conditions studied

1

Description of health condition studied
breast reconstruction surgery
ICD-10 code
N65.0
ICD-10 code description
Deformity of reconstructed breast

Primary outcomes

1

Description
The severity of the pain
Timepoint
After surgery
Method of measurement
VAS scoring system

Secondary outcomes

1

Description
Nausea
Timepoint
After surgery
Method of measurement
Patient comment

2

Description

Vomiting

Timepoint

After surgery

Method of measurement

Patient comment

Intervention groups

1

Description

Intervention group: After standard monitoring, patients are anesthetized with intravenous drugs. After the surgery, the patients are placed under a nerve block in one of two ways. In the pectoral nerve block group, after the surgery, the ultrasound probe is placed on the Infraclavicular area and moved to the artery and the axillary vein above the first rib to the outside just above the junction of the pectoralis major and minor muscles at the window location. The syringe is then inserted between the two muscles and 10 ml of ropivacaine ۰/۲% is injected to block the internal pectoral nerve as well as the external pectoral nerve .

Category

Treatment - Other

2

Description

Control group: After standard monitoring, patients are anesthetized with intravenous drugs. After the surgery, the patients are placed under a nerve block in one of two ways.In the second groop the nerve block is performed by the surgeon himself and in the final stages before the surgery. Before the skin is sutured, the surgeon injects 3 cc of Ropevacaine ۰/۲% in three spaces between the T3 and T5 ribs in each space, and the injection time is recorded.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Faranak Rokhtabnak

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Iran University of Medical Sciences., Hemmat Highway., Next to Milad Tower., Tehran Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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

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

Faranak Rokhtabnak

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Iran University of Medical Sciences
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Associate professor
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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