

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 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)

Phone

+98 21 8894 6267

Email address

rolhtabnak.f@iums.ac.ir

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

AgeFrom **18 years** old to **50 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample sizeTarget 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 0.2% 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 group 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 Ropivacaine 0.2% 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Abbas Motavalian

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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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Faranak Rokhtabnak
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Latest degree
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Person responsible for updating data

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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