

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluation the efficacy of serratus anterior block on post mastectomy and mammoplasty pain

#### Protocol summary

##### Summary

Objective: the recent study is conducted for evaluating of the efficacy of serratus anterior block as an easier and safer method. 60 Patients will be divided in two groups randomized. Design and Participants : Inclusion criteria are: patients with 20-60 years of age will be candidate for the elective breast surgery; ASA class I-II. Exclusion criteria: Emergency surgery; Patient refusal; Coagulopathy; Addiction to any opioids or psychoactive drugs; Anxiety disorders or depression; Any intraoperative complication. Intervention: Only in under studying group, sonographic guided anterior serratus block is made with 0.3 cc/kg of bupivacaine 0.2%, and then IV infusion pump is prescribed with the volume of 50 cc (fentanyl 15 cc + normal saline 35 cc) and setting of 2 cc bolus dose and 15 min lock out interval in both group. Main outcomes: Pain score will be recorded at 1 and 2 and 6 and 12 and 24 hours after block. And also IV Apotel will be injected if numeric rating scale  $\geq 3$ . Also the first time and count number of pump usage and total dosage of Fentanyl consumption will be detected and analyzed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016011810599N6**

Registration date: **2017-01-06, 1395/10/17**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-01-06, 1395/10/17

##### Registrant information

###### Name

Poupak Rahimzadeh

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6650 9059

##### Email address

p-rahimzadeh@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research Iran University Of Medical Sciences

##### Expected recruitment start date

2016-11-03, 1395/08/13

##### Expected recruitment end date

2017-03-03, 1395/12/13

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation the efficacy of serratus anterior block on post mastectomy and mammoplasty pain

##### Public title

Evaluation the intra chest wall muscle injection effect on post breast surgery

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria... Patients with 20-60 years of age candidates for the elective breast surgery; ASA class I-II  
Exclusion criteria... Emergency surgery; Patient refusal; Coagulopathy; Addiction to any opioids or psychoaffective drugs; Anxiety disorders or depression;

Any intraoperative complication

#### Age

From **20 years** old to **60 years** old

#### Gender

Female

#### Phase

2-3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **60**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

### 1

#### Registry name

-

#### Secondary trial Id

-

#### Registration date

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Iran University of Medical Sciences

##### Street address

Niyayesh Street

##### City

Tehran

##### Postal code

#### Approval date

2010-09-23, 1389/07/01

#### Ethics committee reference number

IR.IUMS.REC.1395.28929

## Health conditions studied

### 1

#### Description of health condition studied

post mastectomy and mamoplasty pain

#### ICD-10 code

S20.0

#### ICD-10 code description

Contusion of breast

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

1 and 6 and 12 and 24 hours after block

#### Method of measurement

VAS (visual analog scale)

## Secondary outcomes

### 1

#### Description

Opioid necessity

#### Timepoint

1 and 6 and 12 and 24 hours after block

#### Method of measurement

The volume of drug use in pain management pumps

## Intervention groups

### 1

#### Description

Intervention group, sonographic guided anterior serratus block is made with 0.3 cc/kg of bupivacaine 0.2%, and then IV infusion pump is prescribed with the volume of 50 cc (fentanyl 15 cc + normal saline 35 cc) and setting of 2 cc bolus dose and 15 min lock out interval.

#### Category

Treatment - Other

### 2

#### Description

Control group, only the infusion pump with the same contents and setting is prescribed

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rasool Akram hospital

##### Full name of responsible person

Rhimzadeh poupak MD

##### Street address

Tehran-Niyayesh street

##### City

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice Chancellor for Research Iran University Of  
Medical Science

**Full name of responsible person**

Dr. Seyed Ali javad Musavi, MD

**Street address**

Tehran-Hemmat Highway

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for Research Iran University Of Medical  
Science

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Valiyan Borujeni Banafshe

**Position**

fellowship

**Other areas of specialty/work****Street address**

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banafshe6937@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

Rahimzadeh Poupak MD

**Position**

Lecturer

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## Person responsible for updating data

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Rahimzade Poupak MD

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**Fax****Email**

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**Web page address**

## 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*