

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

comparison the effect of Erector Spinae Block VS Pectoral 1 Block on post operative pain , nausea and vomiting in breast mass surgeries ; a double blind randomized study

Protocol summary

Study aim

comparison the effect of Erector Spinae Block VS Pectoral 1 Block on post operative pain , nausea and vomiting in breast mass surgeries ; a double blind randomized study

Design

after consent for regional block , qualified person put in table of random numbers.before general anesthesia in aseptic field on sonography guide we did pecs1 block and erector spinae block(20cc rupivacaine .25%).patients received same drugs for general anesthesia.BIS was monitored(40-60).after surgery in full awake patients we measured pain(VAS score),nausa,vomiting.also need for narcotic in post operation was evaluated.

Settings and conduct

after consent for regional block , qualified person put in table of random numbers.before general anesthesia in aseptic field on sonography guide we did pecs1 block and erector spinae block(20cc rupivacaine .25%).patients received same drugs for general anesthesia.BIS was monitored(40-60).after surgery in full awake patients we measured pain(VAS score),nausa,vomiting.also need for narcotic in post operation was evaluated.

Participants/Inclusion and exclusion criteria

women age 18-50 ASA class 1-2 insensitivity to LA No psychotic disorder No addiction no hemostasis disorder no local skin infection no use analgesic and NSAID drugs

Intervention groups

Pecs1 Block Erector Spinae Block

Main outcome variables

need for narcotic HEMODYNAMIC(BP-HR) vomiting nausea pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181126041760N1**

Registration date: **2019-07-23, 1398/05/01**

Registration timing: **retrospective**

Last update: **2019-07-23, 1398/05/01**

Update count: **0**

Registration date

2019-07-23, 1398/05/01

Registrant information

Name

Houman Teymourian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2274 1174

Email address

houman72625@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-08, 1398/02/18

Expected recruitment end date

2019-07-13, 1398/04/22

Actual recruitment start date

2019-06-29, 1398/04/08

Actual recruitment end date

2019-07-11, 1398/04/20

Trial completion date

2019-07-13, 1398/04/22

Scientific title

comparison the effect of Erector Spinae Block VS Pectoral 1 Block on post operative pain , nausea and vomiting in breast mass surgeries ; a double blind randomized study

Public title

comparison the effect of Erector Spinae Block VS Pectoral 1 Block on post operative pain , nausea and vomiting in breast mass surgeries ; a double blind randomized study

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

women age 18-50 ASA class 1-2 insensitivity to LA No psychotic disorder No addiction no hemostasis disorder no local skin infection no use analgesic and NSAID drugs

Exclusion criteria:

operation time more than 4 hours excessive blood loss changing procedure type

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **64**

Actual sample size reached: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Related code was given to all patients by Computer based on Random number table and the patients were divided in two groups (simple randomization) . In one group the second anesthesiologist who wasn't aware from research type, blocked the patients based on closed envelope which include the type of block. The main researcher was not aware about the block was used for each patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and the anesthesiology resident were not aware about type of blocks. although the patient was aware and consent about Nerve block benefits, anesthesiologist who did the block was not participated in complition of questioner.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics research of shahid beheshti university of medical science

Street address

ERABI STREET

City

tehran

Province

Tehran

Postal code

1989934148

Approval date

2019-05-08, 1398/02/18

Ethics committee reference number

IR.SBMU.MSP.REC.1398.094

Health conditions studied

1

Description of health condition studied

Analgesia in chest wall operations

ICD-10 code

N60

ICD-10 code description

benign mammary dysplasia skin of breast

Primary outcomes

1

Description

PAIN

Timepoint

recovery/60minutes after recovery/2hours after recovery/4hours after recovery/6hours after recovery

Method of measurement

visual analogue scale

2

Description

nausea

Timepoint

recovery/60minutes after recovery/2hours after recovery/4hours after recovery/6hours after recovery

Method of measurement

questionnaire

3

Description

vomiting

Timepoint

recovery/60minutes after recovery/2hours after recovery/4hours after recovery/6hours after recovery

Method of measurement

questionnaire

4

Description

Blood Pressure

Timepoint

after injection/15minutes after/30minutes
after/45minutes after/60minutes after/75minutes
after/90minutes after/2hours after/3hours after/4hours
after/6hours after

Method of measurement

BP monitoring (mmhg)

5

Description

herat rate

Timepoint

after injection/15minutes after/30minutes
after/45minutes after/60minutes after/75minutes
after/90minutes after/2hours after/3hours after/4hours
after/6hours after

Method of measurement

HR monitoring

6

Description

need for narcotic

Timepoint

Recovery/60 minutes after recovery/2 hours after
recovery/4 hours after recovery/6 hours after recovery

Method of measurement

patient file (macrogram)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: pecs1 block/ after consent for regional block , qualified person put in table of random numbers.before general anesthesia in aseptic field on sonography guide we did pecs1 block(20cc rupivacaine .25%).patients received drugs for general anesthesia.BIS was monitored(40-60).after surgery in full awake patients we measured pain(VAS score),nausa,need for narcotic,vomiting.

Category

Other

2

Description

Intervention group:erector soinae block/ after consent for regional block , qualified person put in table of random numbers.before general anesthesia in aseptic field on sonography guide we did erector spinae block (20cc

rupivacaine .25%).patients received drugs for general anesthesia.BIS was monitored(40-60).after surgery in full awake patients we measured pain(VAS score),nausa,need for narcotic,vomiting.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Tajrish Hospital

Full name of responsible person

Hooman Teimoorian

Street address

Tajrish Square

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 2274 1174

Email

dr.teymourian@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Houman Teymourian

Street address

Operating room, floor 2, Building 1, Shohada Tajrish hospital, Tajrish squire

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 2274 1174

Fax

+98 21 2274 1174

Email

dr.teymourian@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Houman Teymourian

Position

Associated professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street addressAnesthesia department, Shohada Tajrish hospital,
Shahrdari street, Tajrish squer, Tehran, Iran**City**

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 2274 1174

Fax**Email**

houman72625@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Houman Teymourian

Position

associate professor

Latest degree

Specialist

Other areas of specialty/work

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tajrish square

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Phone

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Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Houman Teymourian

Position

Associated professor

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Other areas of specialty/work

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Phone

+98 21 2274 1174

Fax**Email**

houman72625@yahoo.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

all data will be published without identifying personal identities.

When the data will become available and for how long

almost 6 months after result publication

To whom data/document is available

11 persons

Under which criteria data/document could be used

After contacting with corresponding author, dr.Houman Teymourian

From where data/document is obtainable

Houman Teymourian

What processes are involved for a request to access data/document

1 week after contacting with corresponding author

Houman Teymourian
Comments