

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effect of Intraoperative Infusion of Dexmedetomidine on Acute and chronic postoperative pain after simple mastectomy

#### Protocol summary

##### Study aim

The Effect of Intraoperative Infusion of Dexmedetomidine on Acute and chronic postoperative pain after simple mastectomy

##### Design

Double Blinded Randomized Clinical Trial

##### Settings and conduct

During surgery patients in the operating room in the intervention group received dexmedetomidine infusion of 0.4 mg / kg to control postoperative pain . The infusion is given to the patient.And in the control group: 40 ml distilled water in the syringe is infused into the patient.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria:Patients undergoing simple mastectomy 18-65 years ASA I& II Exclusion criteria:Sensitivity to dexmedetomidine, History of heart failure (EF <40%) ,Kidney Disorders (Creatinine greater than 2), History of liver disease,Psychiatric and cognitive disorders ,Chronic pain ,Drug and cigarette abuse, Psychotropic drugs and forgetfulness, Pregnancy Alcohol abuse, Arthritis, Chronic use of opioids, hypnotics and non-opioid analgesics, Diabetes for more than 10 years.

##### Intervention groups

Intervention group: Dexmedetomidine is injected to the patient at a dose of 0.4 mcg / kg. Control group:40 ml distilled water is injected into the syringe as an infusion.

##### Main outcome variables

Chronic pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141009019470N90**

Registration date: **2019-11-27, 1398/09/06**

Registration timing: **prospective**

Last update: **2019-11-27, 1398/09/06**

Update count: **0**

##### Registration date

2019-11-27, 1398/09/06

##### Registrant information

###### Name

Farzaneh Masihi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3647 4270

###### Email address

masihif@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-12-06, 1398/09/15

##### Expected recruitment end date

2020-03-05, 1398/12/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Intraoperative Infusion of Dexmedetomidine on Acute and chronic postoperative pain after simple mastectomy

##### Public title

The Effect of Intraoperative Infusion of Dexmedetomidine on Acute and chronic postoperative pain after simple mastectomy

##### Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients undergoing simple mastectomy 18-65 years ASA I& II

### Exclusion criteria:

Sensitivity to dexmedetomidine History of heart failure (EF <40%) Kidney Disorders (Creatinine greater than 2) History of liver disease Psychiatric and cognitive disorders Chronic pain Drug and cigarette abuse Psychotropic drugs and forgetfulness Pregnancy Alcohol abuse Arthritis Chronic use of opioids, hypnotics and non-opioid analgesics, Having diabetes for more than 10 years Cases in which the surgeon decides to change the surgical procedure for any reason

## Age

From **18 years** old to **65 years** old

## Gender

Female

## Phase

2-3

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

## Sample size

Target sample size: **110**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients randomized block permutation through 55 were divided into two groups www.Randomization.com site.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The volume of a 2 cc vial of dexmedetomidine is 200 mcg. Therefore, 38 ml of distilled water is added to the dexmedetomidine vial. As a result, each 1 cc is equivalent to 5 mcg and is eventually infused at a dose of 0.4 mcg / kg. The placebo group received 40 ml of distilled water in the syringe as an infusion. The nurse responsible for completing the questionnaires and the nurse responsible for treating patients as well as patients in both groups were not aware of the assignment of patients to the groups.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

## Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

## Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

## City

Shiraz

## Province

Fars

## Postal code

7134844119

## Approval date

2019-07-22, 1398/04/31

## Ethics committee reference number

IR.SUMS.MED.REC.1398.297

## Health conditions studied

### 1

#### Description of health condition studied

Mastectomy

#### ICD-10 code

Z42.1

#### ICD-10 code description

Encounter for breast reconstruction following mastectomy

## Primary outcomes

### 1

#### Description

Acute pain

#### Timepoint

The patient's pain is assessed 24 hours after surgery in the recovery room (on arrival at recovery and at the first and second hours) every 4 hours.

#### Method of measurement

Visual Analogue Scale

### 2

#### Description

Chronic pain

#### Timepoint

Three months after surgery

#### Method of measurement

Brief Pain Inventory

## Secondary outcomes

### 1

#### Description

Total Morphine Consumption

#### Timepoint

Up to 24 hours after surgery

#### Method of measurement

Observation

## Intervention groups

### 1

#### Description

Intervention group: Dexmedetomidine is injected to the patient at a dose of 0.4 mcg / kg.

#### Category

Prevention

### 2

#### Description

Control group:40 ml distilled water is injected into the syringe as an infusion.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahi Faghihi Hospital

##### Full name of responsible person

Maryam Noorizadeh

##### Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

##### City

Shiraz

##### Province

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##### Postal code

7134844119

##### Phone

+98 71 3647 4270

##### Email

dr.maryamnoorizadeh@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Dr. Younes Ghasemi

##### Street address

Vice chancellor of research,7th floor of central building of Shiraz University of Medical Sciences, Zand

##### City

Shiraz

##### Province

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7134844119

##### Phone

+98 71 3647 4270

#### Email

vcrdep@sums.ac

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

##### Full name of responsible person

Maryam Noorizadeh

##### Position

Anesthesiology Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Anesthesiology

##### Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Saeed Khademi

##### Position

Cardio-Anesthesiologist

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

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

Shiraz University of Medical Sciences

**Full name of responsible person**

Farzaneh Masihi

**Position**

BS in anesthesia/English Consultant

**Latest degree**

Master

**Other areas of specialty/work**

Anesthesiology

**Street address**

Anesthesiology Department, Namazi Hospital, Namazi

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Its against our policy.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available