

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Dexmedetomidine on Quality of Recovery after simple mastectomy under General anesthesia

Protocol summary

Study aim

The effect of Dexmedetomidine on Quality of Recovery after simple mastectomy under General anesthesia

Design

Double Blinded Randomized Clinical Trial with Parallel Group

Settings and conduct

Intervention group: Patients in the intervention group will begin 30 min before surgery with a dose of 0.4 mcg / kg for the dexmedetomidine infusion. Control group: Patients in the control group will receive 0.9% normal saline infusion at a rate of 0.1 cc / kg for 30 min before surgery.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients undergoing simple mastectomy surgery Age 25-65 years ASA Class I – II.
Exclusion Criteria: History of heart failure, History of Kidney Failure, History of liver failure, Psychiatric and cognitive disorders, Chronic pain, Drug abuse or using psychotropic drugs, Pregnancy, Alcohol abuse, Long-term use of painkillers History of allergy to dexmedetomidine, Redo surgery, History of motor disease.

Intervention groups

Intervention group: Patients in the intervention group will begin 30 min before surgery with a dose of 0.4 mcg / kg for the dexmedetomidine infusion. Control group: Patients in the control group will receive 0.9% normal saline infusion at a rate of 0.1 cc / kg for 30 min before surgery.

Main outcome variables

Postoperative pain

General information

Reason for update

Since I did not start the clinical trial until the IRCT registration, I changed the expected start date

Acronym

IRCT registration information

IRCT registration number: **IRCT20141009019470N100**

Registration date: **2020-07-18, 1399/04/28**

Registration timing: **prospective**

Last update: **2020-07-28, 1399/05/07**

Update count: **1**

Registration date

2020-07-18, 1399/04/28

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

2020-08-10, 1399/05/20

Expected recruitment end date

2020-10-21, 1399/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Dexmedetomidine on Quality of Recovery after simple mastectomy under General anesthesia

Public title

The effect of Dexmedetomidine on Quality of Recovery

after simple mastectomy under General anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing simple mastectomy surgery Age 25-65 years ASA Class I – II

Exclusion criteria:

History of heart failure History of Kidney Failure History of liver failure Psychiatric and cognitive disorders Chronic pain Drug abuse or using psychotropic drugs Pregnancy Alcohol abuse Long-term use of painkillers History of allergy to dexmedetomidine Redo surgery History of motor disease

Age

From **25 years** old to **65 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were divided into two groups of 55, using the table from www.randomization.org. Patients are divided into groups A and B and treated according to their group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The dexmedetomidine infusion will begin thirty minutes before the end of surgery in the first group. In the second group, 0.9% normal saline infusion will begin 30 minutes before the surgery. While the anesthesiology nurse who provides dexmedetomidine and normal saline syringes and gives them to the anesthesiology resident in the operating room is unaware of the study groups. Data collection is done in the recovery and ward by nursing staff who is unaware of the amount of medication received in 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

2020-02-18, 1398/11/29

Ethics committee reference number

IR.SUMS.MED.REC.1398.633

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

The agitation

Timepoint

It is examined every 30 minutes for 2 hours in recovery as well as after the patient is transferred to ward every 2 to 6 hours

Method of measurement

Ramsay criteria

2

Description

Nausea and vomiting

Timepoint

It is examined every 30 minutes for 2 hours in recovery as well as after the patient is transferred to ward every 2 to 6 hours

Method of measurement

Likert

3

Description

Postoperative pain

Timepoint

It is examined every 30 minutes for 2 hours in recovery

as well as after the patient is transferred to ward every 2 to 6 hours

Method of measurement

Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:30 minutes before surgery, dexmedetomidine infusion will start at a dose of 0.4 mcg / kg.

Category

Prevention

2

Description

Control group:The 0.9% normal saline infusion will start at 0.1 cc / kg 30 min before surgery.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Faghihi Hospital

Full name of responsible person

Ayda Najafi Kashkooli

Street address

Faghihi Hospital, Zand Street

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7134844119

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+98 71 3235 1087

Email

faghihihsp@sums.ac.ir

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,

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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

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

Ayda Najafi Kashkooli

Position

Anesthesiology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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ida_najafi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Saied Khademi

Position

Cardio-anesthesiologist

Latest degree

Subspecialist

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

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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 policies.

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