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

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Iran (Islamic Republic of)

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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

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Province

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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

Observasion

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
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Sponsors / Funding sources

1

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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
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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 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