

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Title: Effect of Clonidine on Post-operative Nausea and Vomiting in Breast Cancer Surgery

Protocol summary

Study aim

Effect of Clonidine on Post-operative Nausea and Vomiting in Breast Cancer Surgery

Design

Double blinded randomized clinical trial

Settings and conduct

Intervention group: Patients are given 0.2 mg of clonidine tablets in the morning. Control group: Patients are given one tablet in the morning as a placebo. (Made by Shiraz University of Medical Sciences School of Pharmacy), which is similar to clonidine tablets.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients Candidate for Breast Cancer Surgery, Ages 15 to 70 years, ASA Class I-II General Anesthesia. Exclusion criteria: A history of postoperative nausea and vomiting, Patients who have received antiemetic drugs such as ondansetron or dexamethasone 24 hours before surgery, History of motion sickness, Allergy to Propofol and Clonidine, Concomitant use of beta-blocker medication that may affect a patient's heart rate, Systolic blood pressure less than 100, History of using Steroid, History of myocardial infarction, History of tricyclic antidepressant use, History of kidney dysfunction.

Intervention groups

Intervention group: Patients are given 0.2 mg of clonidine tablets in the morning. Control group: Patients are given one tablet in the morning as a placebo. (Made by Shiraz University of Medical Sciences School of Pharmacy), which is similar to clonidine tablets.

Main outcome variables

Post-operative Nausea and Vomiting, Hemodynamic changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141009019470N99**

Registration date: **2020-06-18, 1399/03/29**

Registration timing: **prospective**

Last update: **2020-06-18, 1399/03/29**

Update count: **0**

Registration date

2020-06-18, 1399/03/29

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

2020-07-21, 1399/04/31

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Title: Effect of Clonidine on Post-operative Nausea and Vomiting in Breast Cancer Surgery

Public title

Title: Effect of Clonidine on Post-operative Nausea and

Vomiting in Breast Cancer Surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients Candidate for Breast Cancer Surgery Ages 15 to 70 years ASA Class I-II General Anesthesia

Exclusion criteria:

A history of postoperative nausea and vomiting Patients who have received antiemetic drugs such as ondansetron or dexamethasone 24 hours before surgery History of motion sickness Allergy to Propofol and Clonidine Concomitant use of beta-blocker medication that may affect a patient's heart rate Systolic blood pressure less than 100 History of using Steroid History of myocardial infarction History of tricyclic antidepressant use History of kidney dysfunction

Age

From **15 years** old to **70 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two groups of four permutation blocks based on a randomization table from Randomization.com.

Blinding (investigator's opinion)

Double blinded

Blinding description

A nurse in the ward gives patients clonidine or placebo tablets one hour before the patient enters the operating room on a randomized basis. The patient, an individual assessment of the patient in the operating room , recovery room and ward nurses and are unaware of the study 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

2020-03-01, 1398/12/11

Ethics committee reference number

IR.SUMS.MED.REC.1398.653

Health conditions studied

1

Description of health condition studied

Breast Cancer

ICD-10 code

D05.10

ICD-10 code description

Intraductal carcinoma in situ of unspecified breast

Primary outcomes

1

Description

Post-operative Nausea and Vomiting

Timepoint

Postoperative nausea and vomiting in recovery is recorded at 0-15-30 and 45 minutes. After transferring the patient to the surgical ward, the incidence of postoperative nausea and vomiting is evaluated at 6 and 24 hours.

Method of measurement

Likert

Secondary outcomes

1

Description

Hemodynamic changes

Timepoint

Blood pressure and heart rate are recorded in the surgical ward in the operating room before induction after induction and in recovery at 0-15-30 and 45 minutes. After transferring the patient to the surgical ward, the patient's blood pressure is checked at 24,2,4,6,12 hours.

Method of measurement

Monitoring

Intervention groups

1

Description

Intervention group: Patients are given 0.2 mg of clonidine tablets in the morning.

Category

Prevention

2

Description

Control group: Control group: Patients are given one tablet in the morning as a placebo. (Made by Shiraz University of Medical Sciences School of Pharmacy), which is similar to clonidine tablets.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Faghihi Hospital

Full name of responsible person

Shabnam Heiydarinezhad

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Zand Street, Faghihi Hospital

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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, Zand street

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sacrc@sums.ac.ir

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

Shabnam Heidarynezhad

Position

Anesthesiology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Ali Akbari

Position

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

5th floor, Mohammad Rasoul Allah Research Tower, Khalili Street

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