Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Perioperative Lidocaine versus Dexmedetomidine on Depressive Symptoms and Sleep Quality Following Breast Cancer Surgery

Protocol summary

Study aim

Intravenous lidocaine and dexmedetomidine for depressive symptoms and sleep quality after breast cancer surgery.

Design

In a controlled, parallel-group, double-blind clinical trial, 120 patients will be randomized 1:1 to either lidocaine (Group L) or dexmedetomidine (Group D) using a random number generator.

Settings and conduct

This study will enroll female breast cancer surgery candidates aged 18–60 years with ASA physical status I–II at Shohada-ye Tajrish Hospital, following University Ethics Committee approval and written informed consent. Participants must exhibit mild to severe anxiety and/or depression, defined as scores >5 on the GAD-7 and PHQ-9 questionnaires. After anesthesia induction, patients will receive either intravenous dexmedetomidine (1 µg/kg loading dose, followed by a 0.5–1 µg/kg/h continuous infusion) or lidocaine (1.5 mg/kg loading dose, followed by a 1.5–2 mg/kg/h continuous infusion) until recovery room discharge. Postoperative follow-up will occur at 24 hours, 3 days, and 1 week.

Participants/Inclusion and exclusion criteria

Eligible female patients aged 18-60 years, with ASA class I-II undergoing cancer surgery, presented with mild to severe anxiety or depression (GAD-7 and PHQ-9 scores > 5).

Intervention groups

Patients will be randomized 1:1 to either lidocaine (Group L) or dexmedetomidine (Group D).

Main outcome variables

Reduced depression and anxiety symptoms, improved sleep quality in the first postoperative week, lower pain scores and opioid consumption, and fewer adverse effects.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250722066589N4**
Registration date: **2026-02-03, 1404/11/14**
Registration timing: **registered_while_recruiting**

Last update: **2026-02-03, 1404/11/14**
Update count: **0**

Registration date

2026-02-03, 1404/11/14

Registrant information

Name

Malihe Abniki

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-01-31, 1404/11/11

Expected recruitment end date

2026-05-22, 1405/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Perioperative Lidocaine versus Dexmedetomidine on Depressive Symptoms and Sleep Quality Following Breast Cancer Surgery

Public title
Effect of Perioperative Lidocaine versus Dexmedetomidine on Depressive Symptoms and Sleep Quality Following Breast Cancer Surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Mild to severe anxiety or depression symptoms Without systemic disease, or with controlled systemic disease
Exclusion criteria:
Patients with incomplete clinical data severe cardiac disease increased intracranial pressure epilepsy incomplete clinical data failure to complete the one-week follow-up allergy to intravenous anesthetic agents
Age
From **18 years** old to **60 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
The allocation list is generated using block randomization with random number generator software, employing fixed or variable block sizes (e.g., 4 and 6) to ensure balanced patient numbers between groups. Allocation codes are placed in sequentially numbered, opaque, light-proof envelopes prepared by an independent individual uninvolved in patient treatment or evaluation. Only the admitting personnel in the operating room may open the envelope corresponding to the patient's number.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study employs a double-blind design, ensuring that patients and outcome assessors are unaware of the intervention type. An anesthesia nurse, independent of the data collection team, prepares lidocaine and dexmedetomidine to be identical in appearance (50 mL volume and color) and administers them via identically labeled syringes or infusion pumps with a random code. The research team will remain blinded until the observation period concludes, unless anesthesiologists detect clear signs of systemic toxicity or cardiovascular complications (e.g., severe bradycardia or hypotension).
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Vice-Chancellor in Research Affairs-Shahid Beheshti University of Medi
Street address
5th Floor , Vic President for Research and Tecnology , Shahid Beheshti University of Medical Sciences, Arabi Street, Yemen Street
City
Tehran
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Tehran
Postal code
198571734
Approval date
2026-01-11, 1404/10/21
Ethics committee reference number
IR.SBMU.RETECH.REC.1404.936

Health conditions studied

1

Description of health condition studied
Breast Cancer
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

2

Description of health condition studied
Depressive episode
ICD-10 code
F06.32
ICD-10 code description
Mood disorder due to known physiological condition with major depressive-like episode

3

Description of health condition studied
Sleep disorders
ICD-10 code
G47
ICD-10 code description
Sleep disorders

4

Description of health condition studied
Generalized Anxiety Disorder
ICD-10 code
F41.1
ICD-10 code description
Generalized anxiety disorder

Primary outcomes

1

Description
Changes in NRS scores, opioid use, and adverse events (including cardiac complications, nausea, and dizziness).
Timepoint
During the first 24 hours after surgery
Method of measurement
Numerical Rating Scale

Secondary outcomes

1

Description
depressive symptoms
Timepoint
on postoperative days 1, 3, and 7
Method of measurement
Patient Health Questionnaire–9 (PHQ-9)

2

Description
Postoperative sleep quality improvement based on PSQI score
Timepoint
on postoperative days 1, 3, and 7
Method of measurement
The Pittsburgh Sleep Quality Index (PSQI) questionnaire

3

Description
anxiety symptoms
Timepoint
on postoperative days 1, 3, and 7
Method of measurement
The 7-item Generalized Anxiety Disorder (GAD-7)

Intervention groups

1

Description
The intervention group will receive intravenous dexmedetomidine. After induction of anesthesia, dexmedetomidine will be administered at a dose of 1 microgram per kilogram, followed by continuous infusion at a rate of 0.5–1 microgram per kilogram per hour until discharge from the recovery room.
Category
Treatment - Drugs

2

Description
The control group will receive intravenous lidocaine. After induction of anesthesia, lidocaine will be administered at a dose of 1.5 mg per kilogram as a loading dose, followed by continuous infusion at a rate of 1.5–2 mg per kilogram per hour until discharge from the recovery room.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada-y- Tajrish hospital
Full name of responsible person
Malihe Abniki
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Sponsors / Funding sources

1

Sponsor
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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
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
Malihe Abniki

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

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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 collected from the study population can potentially be shared after de-identification of individuals.

When the data will become available and for how

long

The access period begins 6 months after publication of the results

To whom data/document is available

Study data will be available to researchers employed in academic and scientific institutions, and also to those employed in industry.

Under which criteria data/document could be used

All data from our study will be available to researchers employed in academic and scientific institutions, and individuals working in industry may also apply to obtain access to the data.

From where data/document is obtainable

Dr Mlihe Abniki

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

Data will be available six months after publication via email or written request.

Comments