

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison Of Pre-Operative Administration Of Oral Duloxetine Versus Placebo For Post-Operative Pain Management And Quality Of Recovery In Modified Radical Mastectomy

Protocol summary

Study aim

our study aims to compare the patients pre-treated with oral duloxetine planned for elective modified radical mastectomy to placebo for quality of recovery, pain scores and reduced rescue analgesia requirements post-operatively.

Design

Quasi-experimental comparative study

Settings and conduct

Department of Anesthesia, Combined Military Hospital, Rawalpindi for at least 3 months or till completion of minimum sample size

Participants/Inclusion and exclusion criteria

INCLUSION CRITERIA: • Will include all ASA II and III female patients aged 18-60 years of age, diagnosed with non-metastatic breast cancer planned for an elective modified radical mastectomy and referred to the anesthesia clinic for pre-anesthesia assessment

EXCLUSION CRITERIA: • Will include patients with metastatic disease, already on anti-depressants or anti-psychotic treatment, patients with severe depression, patients with debilitating hypertension and/or uncontrolled diabetes.

Intervention groups

They will be divided into Group A (n=40) to receive oral duloxetine and Group B (n=40) to receive placebo tablet not containing any active drug but used to ensure blinding and prevent bias.

Main outcome variables

After the surgical procedure, patients will be kept in the high dependency unit (HDU) for observation. Primary variable would be patient recovery assessed at 3,6,12 and 24 hours after the procedure using the QoR-40 scoring system which will include assessment of patient support, comfort, emotions, physical independence, and pain with a total score ranging from 40-200 with higher scores associated with better patient recovery.

Secondary variables will be pain scores assessed using 10-point Visual Analog Scale (VAS) assessed at 3,6,12 and 24 hours post-surgery and total dose of IV Morphine used in 24 hours as rescue analgesia once pain scores will be above 6 on the VAS.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260627069964N1**

Registration date: **2026-07-02, 1405/04/11**

Registration timing: **registered_while_recruiting**

Last update: **2026-07-02, 1405/04/11**

Update count: **0**

Registration date

2026-07-02, 1405/04/11

Registrant information

Name

Adnan Amjad Malik

Name of organization / entity

Combined Military Hospital Multan, Pakistan

Country

Pakistan

Phone

+92 333 4380864

Email address

adnanmalik1994@hotmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-07-01, 1405/04/10

Expected recruitment end date

2026-09-30, 1405/07/08
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison Of Pre-Operative Administration Of Oral Duloxetine Versus Placebo For Post-Operative Pain Managment And Quality Of Recovery In Modified Radical Mastectomy

Public title
Comparison Of Pre-Operative Administration Of Oral Duloxetine Versus Placebo For Post-Operative Pain Managment And Quality Of Recovery In Modified Radical Mastectomy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Will include all ASA II and III female patients aged 18-60 years of age Patients diagnosed with non-metastatic breast cancer planned for an elective modified radical mastectomy and referred to the anesthesia clinic for pre-anesthesia assessment
Exclusion criteria:
Will include patients with metastatic disease Patients already on anti-depressants or anti-psychotic treatment Patients with severe depression Patients with debilitating hypertension and/or uncontrolled diabetes.

Age
From **18 years** old to **60 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
A written informed high risk consent will be taken from all patients due to nature of the surgical procedure as per standard operative guidelines. They will be divided into Group A (n=40) to receive oral duloxetine and Group B (n=40) to receive placebo tablet not containing any active drug but used to ensure blinding and prevent bias. Patients in Group A will be given Tab Duloxetine 30 mg 12 hourly for 7 days before surgery whereas patients in Group B will be given tablets as placebo in the same time intervals.

Placebo
Used

Assignment
Parallel
Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Combined Military Hospital Rawalpindi
Street address
Rawalpindi Cantt
City
Rawalpindi
Postal code
000000
Approval date
2024-11-11, 1403/08/21
Ethics committee reference number
719

Health conditions studied

1
Description of health condition studied
MODIFIED RADICAL MASTECTOMY
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1
Description
Primary variable would be patient recovery assessed at 3,6,12 and 24 hours after the procedure using the QoR-40 scoring system which will include assessment of patient support, comfort, emotions, physical independence, and pain with a total score ranging from 40-200 with higher scores associated with better patient recovery.
Timepoint
3,6,12 and 24 hours after the procedure
Method of measurement
using the QoR-40 scoring system which will include assessment of patient support, comfort, emotions, physical independence, and pain with a total score ranging from 40-200

Secondary outcomes
empty

Intervention groups

1

Description

Intervention group: The patients in Group A will be given Tab Duloxetine 30 mg 12 hourly for 7 days before surgery. Patients non-compliant on medication in pre-operatively will be excluded from the study protocol. After the surgical procedure, patients will be kept in the high dependency unit (HDU) for observation.

Category

Treatment - Drugs

2

Description

Control group: These patients will receive placebo tablet not containing any active drug but used to ensure blinding and prevent bias. They will be given tablets as placebo in the same time intervals. Patients non-compliant on medication in pre-operatively will be excluded from the study protocol. After the surgical procedure, patients will be kept in the high dependency unit (HDU) for observation.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Anesthesia, Combined Military Hospital, Rawalpindi

Full name of responsible person

Adnan Amjad Malik

Street address

Rawalpindi cantt

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Combined Military Hospital, Rawalpindi

Full name of responsible person

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Grant name

Nil

Grant code / Reference number

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

Yes

Title of funding source

Combined Military Hospital, Rawalpindi

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

Combined Military Hospital, Rawalpindi

Full name of responsible person

Adnan Amjad Malik

Position

Resident anaesthesia

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Combined Military Hospital Multan, Pakistan

Full name of responsible person

Adnan Amjad Malik

Position

Resident Anesthesia

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Medical doctor
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Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
Adnan Amjad Malik
Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

"COMPARISON OF PRE-OPERATIVE ADMINISTRATION OF ORAL DULOXETINE VERSUS PLACEBO FOR POST-OPERATIVE PAIN MANAGEMENT AND QUALITY OF RECOVERY IN MODIFIED RADICAL MASTECTOMY"

When the data will become available and for how long

After publication of study

To whom data/document is available

Journal publishing it

Under which criteria data/document could be used

Journal publishing it

From where data/document is obtainable

Journal publishing it

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

Once study is completed and published in a journal

Comments