Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison Of Pre-Operative Administration Of Oral Duloxetine Versus Placebo For Post-Operative Pain Managament 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

Recruitment complete

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 Managament And Quality Of Recovery In Modified Radical Mastectomy

Public title

Comparison Of Pre-Operative Administration Of Oral Duloxetine Versus Placebo For Post-Operative Pain Managament 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Combined Military Hospital, Rawalpindi
Full name of responsible person
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Street address
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Email
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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
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Person responsible for scientific inquiries

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Position
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Person responsible for updating data

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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 MANAGAMENT 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