Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

Comparison of Mirtazapine and Olanzapine on Nausea and Vomiting following Anthracycline-Cyclophosphamide Chemotherapy Regimen in Patients with Breast Cancer

Protocol summary

Study aim

Determining the Efficacy and Safety of Two Mirtazapine and Olanzapine-based Therapeutic Regimens for the Prevention of Nausea and Vomiting following Anthracyline, Cyclophosphamide Chemotherapy Regimen in Patients with Breast Cancer

Design

Randomized Clinical Trial with Two Study Arms, with Parallel and Double blinded Groups

Settings and conduct

This clinical Trial Study will be performed on Patients with Breast Cancer admitted to the Oncology Ward of Taleghani and Baqiyatallah Hospitals in Tehran. Sixty Patients will be randomly divided into Two Intervention Groups, Mirtazapine (MTZ) and Olanzapine (OLP). Each Group will receive Triple Standard of Care Regimen before Chemotherapy in Addition to MTZ or OLP. The primary Outcomes of Nausea and Vomiting and secondary Outcomes will be measured by the NCI-CTCAE up to Five Days after Chemotherapy in the first Two Cycles.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with newly diagnosed Breast Cancer; Patients aged 18-65; Recipient of Chemotherapy Regimen for at least Two consecutive Cycles; Written informed Consent; Exclusion Criteria: A History of Allergy to Mirtazapine or Olanzapine; A History of MI, Seizures, Arrhythmias, Glaucoma and BMD; Concomitant use of any Drug with Class X and D Interference with the Drugs studied; renal or hepatic Failure

Intervention groups

Intervention Group 1: Triple Standard of Care Regimen [Aprepitant Capsule (125 mg PO OD on Day 1, 80 mg OD on Days 2-3), Granisetron (1 mg IV only on Day 1), Dexametason (12 mg IV only on Day 1)] and Mirtazapine Tablet (15 mg PO OD on Days 1-4); Intervention Group 2: Triple Standard of Care Regimen [Aprepitant Capsule (125 mg PO OD on Day 1, 80 mg OD on Days 2-3), Granisetron (1 mg IV only on Day 1), Dexametason (12 mg IV only on Day 1)] and Olanzapine Tablet (10 mg PO OD on Days 1-4).

Main outcome variables

The Severity of Nausea and Vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100127003210N19**
Registration date: **2020-02-10, 1398/11/21**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-10, 1398/11/21**
Update count: **0**

Registration date

2020-02-10, 1398/11/21

Registrant information

Name

Maria Tavakoli Ardakani

Name of organization / entity

Faculty of pharmacy, Shaid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-15, 1398/10/25

Expected recruitment end date

2020-05-14, 1399/02/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Mirtazapine and Olanzapine on Nausea and Vomiting following Anthracycline-Cyclophosphamide Chemotherapy Regimen in Patients with Breast Cancer

Public title

“Comparison of Mirtazapine and Olanzapine on Nausea and Vomiting following Chemotherapy “

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Newly Diagnosed Breast Cancer Receiving Anthracycline-Cyclophosphamide Chemotherapy Regimen in the adjuvant Setting for at least Two consecutive Cycles Patients aged 18 to 65 Written Informed Consent The Patient is able to read and understand the Questionnaires used in the Study

Exclusion criteria:

A History of Allergy to Mirtazapine or Olanzapine Patient with History of Dementia, peptic Ulcer, myocardial Infarction, Seizure, Arrhythmia, Glaucoma, and bipolar Disorder Concomitant use of any Drug with Class X and D Interaction with the Drugs studied Increased basal Creatinine (SrCr ≥ 1.5) or AST or ALT ≥ 3ULN Brain Metastasis or Metastases with gastrointestinal Obstruction Having Nausea and Vomiting within 24 hours prior to Chemotherapy Patients with Disabilities taking oral Medications On chronic antiemetic Therapy (e.g.Metoclopramide); on long Term use of systemic Steroids prior to Chemotherapy Uncontrolled Diabetes The Patient has a History of any Illness that, in the Opinion of the Investigator, might confound the Results of the Study or pros unwarranted Risk

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Individual Randomization with the Card in Two Groups A and B, in this Way a Number of Cards are selected as the first Intervention Group and the same Number in the second Intervention Group, then by merging the Cards together one Card is drawn and its Allocation is recorded and the Card is returned to the other Cards after it has been removed. The Cards are then re-merged and another Card is withdrawn. The Process continues until a Random Sequence Sample Size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

Double blinding will be done for the Intervention.Groups will be designated as A and B, so the Principle Investigator, Outcome Assessor and Data Analyzer will not know how Patients are assigned.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti School of Pharmacy, Niayesh Highway, Valiasr Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-11-04, 1398/08/13

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1398.210

Health conditions studied

1

Description of health condition studied

Patient with breast cancer

ICD-10 code

C50.919

ICD-10 code description

Malignant neoplasm of unspecified site of unspecified female breast

Primary outcomes

1

Description
Severity of Nausea in the Group receiving Mirtazapine
Timepoint
During the Acute Phase [0-24 hours after chemotherapy (CT)], the Delayed (24-120 hours after CT) and the overall (0-120 hours after CT) phases for two CT cycles (each cycle is 21 days)
Method of measurement
National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE) Version 5.0

2

Description
Severity of Nausea in the Group receiving Olanzapine
Timepoint
During the Acute Phase [0-24 hours after chemotherapy (CT)], the Delayed (24-120 hours after CT) and the overall (0-120 hours after CT) phases for two CT cycles (each cycle is 21 days)
Method of measurement
National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE) Version 5.0

3

Description
Comparison of the Severity of Nausea in Two Groups receiving Mirtazapine and Olanzapine
Timepoint
During the Acute Phase [0-24 hours after chemotherapy (CT)], the Delayed (24-120 hours after CT) and the overall (0-120 hours after CT) phases for two CT cycles (each cycle is 21 days)
Method of measurement
National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE) Version 5.0

4

Description
Severity of Vomiting in the Group receiving Mirtazapine
Timepoint
During the Acute Phase [0-24 hours after chemotherapy (CT)], the Delayed (24-120 hours after CT) and the overall (0-120 hours after CT) phases for two CT cycles (each cycle is 21 days)
Method of measurement
National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE) Version 5.0

5

Description
Severity of Vomiting in the Group receiving Olanzapine
Timepoint
During the Acute Phase [0-24 hours after chemotherapy (CT)], the Delayed (24-120 hours after CT) and the overall (0-120 hours after CT) phases for two CT cycles (each cycle is 21 days)
Method of measurement
National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE) Version 5.0

6

Description
Comparison of the Severity of Vomiting in Two Groups receiving Mirtazapine and Olanzapine
Timepoint
During the Acute Phase [0-24 hours after chemotherapy (CT)], the Delayed (24-120 hours after CT) and the overall (0-120 hours after CT) phases for two CT cycles (each cycle is 21 days)
Method of measurement
National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE) Version 5.0

Secondary outcomes

1

Description
Comparison of The Quality of Life in Two Groups receiving Mirtazapine and Olanzapine
Timepoint
120 Hours after Initiation of Chemotherapy
Method of measurement
18-item Functional Living Index-Emesis (FLIE) Questionnaire

2

Description
Severity of adverse Events in the Group receiving Mirtazapine
Timepoint
During the Acute Phase [0-24 Hours after Chemotherapy (CT)], the Delayed (24-120 Hours after CT) and the Overall (0-120 Hours after CT) Phases for Two CT Cycles (each Cycle is 21 Days)
Method of measurement
National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE) Version 5.0

3

Description
Severity of adverse Events in The Group receiving Olanzapine
Timepoint
During the Acute Phase [0-24 Hours after Chemotherapy (CT)], the Delayed (24-120 Hours after CT) and the Overall (0-120 Hours after CT) Phases for Two CT Cycles (each Cycle is 21 Days)
Method of measurement
National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE) Version 5.0

4

Description
Comparison of the Severity of adverse Events in Two Groups receiving Mirtazapine and Olanzapine

Timepoint
During the Acute Phase [0-24 Hours after Chemotherapy (CT)], the Delayed (24-120 Hours after CT) and the Overall (0-120 Hours after CT) Phases for Two CT Cycles (each Cycle is 21 Days)
Method of measurement
National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE) Version 5.0

5

Description
Comparison of the Severity of Somnolence in Two Groups receiving Mirtazapine and Olanzapine
Timepoint
During the Acute Phase [0-24 Hours after Chemotherapy (CT)], the Delayed (24-120 Hours after CT) and the Overall (0-120 Hours after CT) Phases for Two CT Cycles (each Cycle is 21 Days)
Method of measurement
National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE) Version 5.0

6

Description
Comparison of the Severity of Anorexia in Two Groups receiving Mirtazapine and Olanzapine
Timepoint
During the Acute Phase [0-24 Hours after Chemotherapy (CT)], the Delayed (24-120 Hours after CT) and the Overall (0-120 Hours after CT) Phases for Two CT Cycles (each Cycle is 21 Days
Method of measurement
National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE) Version 5.0

Intervention groups

1

Description
Intervention group 1: Eligible patients will receive: Triple Standard of Care Regimen [Aprepitant Capsule (125 mg PO OD on day 1, 80 mg OD on days 2-3), Granisetron (1 mg IV only on day 1), Dexametason (12 mg IV only on day 1)] and Mirtazapine Tablet (15 mg PO OD on days 1-4). The first Day of Chemotherapy begins Half an Hour to an Hour before Chemotherapy.
Category
Prevention

2

Description
Intervention group 2: Eligible Patients will receive Triple Standard of Care Regimen [Aprepitant Capsule (125 mg PO OD on Day 1, 80 mg OD on Days 2-3), Granisetron (1 mg IV only on Day 1), Dexametason (12 mg IV only on Day 1)] and Olanzapine Tablet (10mg PO OD on Days 1-4). The first Day of Chemotherapy begins Half an Hour to an Hour before Chemotherapy. In Patients at Risk of Sedation, the Dose of Olanzapine is considered to be 5 mg.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Medical Oncology, Ayatollah Taleghani hospital
Full name of responsible person
Mojtaba Ghadiany
Street address
Department of Medical Oncology, Taleghani hospital, Erabi St, Shahid Chamran Highway,Tehran, Iran
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2

Recruitment center
Name of recruitment center
Department of Medical Oncology, Baghiyyatollah al-Azam hospital
Full name of responsible person
Mojtaba Ghadiany
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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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
Maria Tavakoli-Ardakani
Position
Associate Professor
Latest degree
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Person responsible for updating data

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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

اطلاعات محرمانه است

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