

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 Anthracycline, 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 ≥ 3 ULN 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

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Postal code

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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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Department of Medical Oncology, Baghiyyatollah al-Azam hospital, Mollasadra St, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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

Specialist

Other areas of specialty/work

Clinical Pharmacy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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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