

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

The effect of Olanzapine on chemotherapy induced nausea and vomiting in patients with cancer : A randomized clinical trial

Protocol summary

Study aim

The purpose of this study was to determine the effect of olanzapine on the prevention of nausea and vomiting induced by chemotherapy in cancer patients.

Design

In this study, 150 eligible patients with cancer admitted in the hematology and oncology ward of Imam Khomeini Hospital of Urmia are chosen. Patients will be randomly assigned into two groups of control and intervention, each patient will have a special code

Settings and conduct

This double-blind study aimed to determine the effect of Olanzapine on the prevention of nausea and vomiting in cancer patients admitted to the hematology and oncology ward of Urmia Imam Khomeini Hospital. Patients were randomly assigned to the intervention and control groups. For the control group, routine anti-vomiting treatment with placebo and for the intervention group in addition to the routine anti-vomiting drugs, Olanzapine tablets will be prescribed. The daily dose of Olanzapine will be for patients with weight less than 60 kg and more than 60 kg; 5 mg and 10 mg, respectively. patients will be received the tablets one day before the start of chemotherapy until the fifth day (for a total of 6 days) for three periods of chemotherapy.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with over than 18 years; patients with cancer who are undergoing chemotherapy for the first time. Exclusion criteria: having the allergy to olanzapine; patients with radiography and operated; diabetic patients; hyperlipidemia

Intervention groups

The study will be conducted with the participation of two groups of patients with cancer. The intervention group, which will receive the common anti-vomiting treatment with olanzapine and the control group, will receive a common anti-vomiting treatment with placebo.

Main outcome variables

nausea and vomiting

General information

Reason for update

Acronym

chemotherapy induced nausea and vomiting(CINV)

IRCT registration information

IRCT registration number: **IRCT20170814035697N3**

Registration date: **2018-03-16, 1396/12/25**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-16, 1396/12/25**

Update count: **0**

Registration date

2018-03-16, 1396/12/25

Registrant information

Name

Hamdolah Sharifi

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Urmia University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Olanzapine on chemotherapy induced nausea and vomiting in patients with cancer : A randomized clinical trial

Public title

"The effect of Olanzapine on chemotherapy induced nausea and vomiting"

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years old. Chemotherapy due to cancer for the first time

Exclusion criteria:

Having allergic to olanzapine Patients under Radiotherapy Patients with surgical history Diabetic patients hyperlipidemia

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Using random allocation software, patients will be randomized into an intervention or a placebo groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher and patients are blind in this study. The investigator and the patients will be unaware of the patients belong to intervention or placebo groups.

Placebo

Used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical

Sciences

Street address

Urmia University of Medical Sciences; Resalat Ave; Jahad Blvd; Urmia; West Azerbaijan Province; Iran

City

Urmia

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West Azarbaijan

Postal code

5714783734

Approval date

2017-07-19, 1396/04/28

Ethics committee reference number

lr.umsu.rec.1396.131

Health conditions studied

1

Description of health condition studied

Chemotherapy induced nausea and vomiting

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

Primary outcomes

1

Description

The nausea and vomiting severity

Timepoint

The before, first, third and fifth days of chemotherapy

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

intervention group: routine treatment + olanzapine tablets with a dose of 5 mg for patients less than 60 kg and 10 mg for patients over 60 kg one day before the start of chemotherapy until the fifth day of therapy (total 6 days)

Category

Treatment - Drugs

2

Description

Control group: Routine anti-vomiting treatment with placebo

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Imam Khomeini Hospital

Full name of responsible person

Hamdolah Sharifi

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Imam Khomeini hospital; Ershad Ave; Modarres Blvd;
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

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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

Oroumia 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**

Oroumia University of Medical Sciences

Full name of responsible person

Hamdolah Sharifi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available