

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Assesment of the effect of Olanzapine on the prevention of radiotherapy-induced nausea and vomiting in patients with abdominal cancers

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 radiotherapy in patients with abdominal cancer

Design

In this study, 60 eligible patients with abdominal cancer in the radiotherapy clinic 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

The study will be double-blind. The treating physician and the researcher will randomly place patients in the control and intervention groups. The control group will be prescribed the usual antiemetic treatment with a placebo. For the intervention group, in addition to the usual antiemetic drugs, olanzapine tablets at a dose of 5 mg for patients under 60 kg and olanzapine 10 mg tablets for patients over 60 kg, one day before the start of radiotherapy until the fifth day of treatment (6 days in total) Will. Patients and questioners will not know the type of groups. The questionnaires will be completed one day before radiotherapy, on the first, third and fifth day or one day after radiotherapy.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Completing the consent form and announcing the cooperation, Age over 18 years old, Radiotherapy Cause of cancer (patients who undergo chemotherapy or surgery in addition to radiotherapy), Radiotherapy for the first time. Exclusion criteria: Patients with proven diabetes, Patients taking anti-lipid drugs, Patients taking antipsychotic drugs, including olanzapine.

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

IRCT registration information

IRCT registration number: **IRCT20170814035697N7**

Registration date: **2022-02-27, 1400/12/08**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-27, 1400/12/08**

Update count: **0**

Registration date

2022-02-27, 1400/12/08

Registrant information

Name

Hamdolah Sharifi

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-15, 1400/10/25

Expected recruitment end date

2022-05-20, 1401/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assesment of the effect of Olanzapine on the prevention of radiotherapy-induced nausea and vomiting in patients with abdominal cancers

Public title

The effect of Olanzapine on the prevention of radiotherapy-induced nausea and vomiting

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Complete the consent form and announce cooperation
Age over 18 years Radiotherapy for cancer (patients undergoing chemotherapy or surgery in addition to radiotherapy) Radiotherapy for the first time

Exclusion criteria:

Patients with proven diabetes Patients taking anti-lipid drugs Patients taking antipsychotic drugs, including olanzapine Pregnant women

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

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

Province

West Azarbaijan

Postal code

5714783734

Approval date

2021-12-01, 1400/09/10

Ethics committee reference number

IR.UMSU.REC.1400.374

Health conditions studied**1****Description of health condition studied**

Radiotherapy 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 radiotherapy

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 radiotherapy 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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Jahad Blvd; Urmia; Iran

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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