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)

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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 Azerbijan Provine; 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

Street address

Imam Khomeini hospital; Ershad Ave; Modarres Blvd; Urmia

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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

Street address

Urmia University of Medical Sciences; Resalat Ave; Jahad Blvd; Urmia; Iran

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mohebbi_iraj@yahoo.co.uk

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