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

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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 Azerbijan Provine; Iran

City
Urmia

Province
West Azarbaijan

Postal code
5714783734

Approval date
2017-07-19, 1396/04/28

Ethics committee reference number
Ir.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; 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
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Urmia University of Medical Sciences; Resalat Ave; 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
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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