Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Investigating the role of Elanzapine in reducing nausea and vomiting caused by chemotherapy in patients undergoing chemotherapy

Protocol summary

Study aim
Investigating the role of olanzapine in reducing nausea and vomiting caused by chemotherapy in patients undergoing chemotherapy

Design
This double-blind randomized clinical trial study with parallel groups will be conducted on 42 patients undergoing chemotherapy with confirmed malignancy in Jahrom city. Patients participating in the study will be divided into two groups using a table of random numbers.

Settings and conduct
Patients referred to Jahrom Cancer Clinic who will undergo chemotherapy will be included in the study. Patients participating in the study will be divided into two groups using a random number table. The person participating in the study, the researcher and the person collecting the data will be unaware of the type of drug used.

Participants/Inclusion and exclusion criteria
Inclusion criteria: People undergoing chemotherapy in Jahrom city with confirmed malignancy who have consented to participate in the study. Non-entry conditions: It includes patients who are hypersensitive to olanzapine and suffer from cognitive diseases and neurological diseases.

Intervention groups
Intervention group 1: They will receive a standard anti-nausea regimen including: 8 mg of intravenous dexamethasone, along with 1 mg of granistrone and aperitnet 125 minutes before chemotherapy on the first day. Also, in the standard regimen, Apritent 80 will be continued on the second and third day, and they will receive 5 mg of olanzapine every morning for 5 days. Intervention group 2: As a control group, the entire protocol of the intervention group is exactly repeated, except that instead of olanzapine, a placebo of the same form as olanzapine tablets containing starch and flour will be used.

Main outcome variables
Complete response to treatment as defined by the absence of nausea and vomiting or the need to receive adjuvant medication

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210415050976N14**
Registration date: **2024-02-19, 1402/11/30**
Registration timing: **retrospective**

Last update: **2024-02-19, 1402/11/30**
Update count: **0**

Registration date
2024-02-19, 1402/11/30

Registrant information
Name
navid kalani
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-01-10, 1402/10/20
Expected recruitment end date
2024-02-09, 1402/11/20
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the role of Elanzapine in reducing nausea and vomiting caused by chemotherapy in patients undergoing chemotherapy

Public title
Investigating the role of Elanzapine in reducing nausea and vomiting caused by chemotherapy in patients undergoing chemotherapy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients over 18 years of age with pathologically or cytologically confirmed malignancy Patients undergoing emtogenic chemotherapy including carboplatin, irinotecan, cyclophosphamide Serum creatinine ≤2.0 mg/dl. Written informed consent
Exclusion criteria:
being pregnant Suffering from cognitive diseases and neurological diseases Treatment with another psychiatric medication such as risperidone, quetiapine, clozapine, phenothiazine, or butyrophenone within 30 days before or during protocol treatment Simultaneous abdominal radiotherapy Simultaneous use of quinolone antibiotic treatment Chronic alcoholism Hypersensitivity to olanzapine Known heart disease
Age
From **18 years** old
Gender
Both

Phase
1-2
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
Generation of random numbers from the table of random numbers: Considering that 42 patients are needed in this study, one number is randomly selected in the table of random numbers and the two digits to the right of it are taken into account, if these two digits are an even number, the patient is assigned to the group intervention, and if there is an individual, he will be assigned to the control group. For example, in the table of random numbers, the number 13 was chosen because 13 is an odd number, so the first sample will be assigned to the control group. In the table, random numbers move in rows from left to right, and with the above pattern, the method of assigning people to two groups is determined.
Blinding (investigator's opinion)
Double blinded
Blinding description
For blinding in the present study, a double-blind method is used so that 1- the person who checks the results and 2- the person who prescribes the drugs do not know which patient received olanzapine. Blinding of the researcher and the patient will be done by placing the drug in similar packages without information about the type of drug.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Jahrom University of Medical Sciences
Street address
Motahari Street, Jahrom University of Medical Sciences
City
Jahram
Province
Fars
Postal code
7167758256
Approval date
2023-10-29, 1402/08/07
Ethics committee reference number
IR.JUMS.REC.1402.083

Health conditions studied

1

Description of health condition studied
Nausea and vomiting caused by chemotherapy
ICD-10 code
R11
ICD-10 code description
Nausea and vomiting

Primary outcomes

1

Description
Complete response to treatment as defined by the absence of nausea and vomiting or the need to receive adjuvant medication
Timepoint
Starting on the first day of treatment with olanzapine

(day-2) and daily until day 5

Method of measurement

Using the Visual Analogue Scale

Secondary outcomes

1

Description

Duration of nausea

Timepoint

Starting on the first day of treatment with olanzapine (day-2) and daily until day 5

Method of measurement

According to the length of time the person has been nauseous

2

Description

Number of vomiting

Timepoint

Starting on the first day of treatment with olanzapine (day-2) and daily until day 5

Method of measurement

According to the number of times the person has vomited

Intervention groups

1

Description

Intervention group 1: They will receive a standard anti-nausea regimen including: 8 mg of intravenous dexamethasone, along with 1 mg of granistrone and aperitnet 125 minutes before chemotherapy on the first day. Also, in the standard regimen, Apritent 80 will be continued on the second and third day, and they will receive 5 mg of olanzapine every morning for 5 days.

Category

Treatment - Drugs

2

Description

Control group: The entire protocol of the intervention group is exactly repeated, except that instead of olanzapine, a placebo of the same form as olanzapine tablets containing starch and flour will be used.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyed al-Shohada Hospital

Full name of responsible person

Mehdi Chegin

Street address

Ostad Motahari Blvd., Seyed al-Shohda Hospital, Jahrom

City

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Province

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Postal code

74157482007

Phone

+98 71 5414 2000

Email

Navidkalani@ymail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Solh joo Cavus

Street address

Jahrom, Shahid Motahari Blvd., Jahrom University of Medical Sciences, Research Assistant

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solhjok@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Jahrom 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

Jahrom University of Medical Sciences

Full name of responsible person

Navid Kalani

Position
Research Expert
Latest degree
Master
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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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