

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation the Effect of Olanzapine on the Nausea and Vomiting Induced by Chemotherapy in Children with Malignancy.

Protocol summary

Study aim

The aim of this study was to evaluate the effect of oral olanzapine on nausea and vomiting due to chemotherapy in children with malignancy.

Design

This study is phase 3 clinical trial, children with malignancy who has inclusion criteria selected on the basis of a medical approval as a study group, based on this, in this study 60 children with inclusion criteria are selected. Patients are randomized and based on blocked methods were categorized, 30 children in the intervention group and 30 children in the placebo group. During the treatment, nausea and vomiting are assessed in three periods.

Settings and conduct

This study was carried out as a clinical trial at the pediatric clinic of Amir Kabir Hospital in Arak city, also the study will be triple blinded in which patients will be blinded in study.

Participants/Inclusion and exclusion criteria

Inclusion criteria include all children aged 5 to 15 years of age with malignancy that recently has been diagnosed with this disease and based on the assessment, diagnosis and approval of physician has indication for chemotherapy, and patients who has a RAS score more than 20 at the first day, has included in the study. Exclusion criteria include diseases that triggers nausea and vomiting and inability to express the severity of nausea and vomiting, also patients who are not satisfied with the study or has olanzapine side effects during the study are excluded from the study.

Intervention groups

In the intervention group, olanzapine is used as an anti-nausea and vomiting drug, and in the control group, the same placebo is used. This medicine is available in 5 milligram pills at a dose of 0.1 mg / kg PO every 24 hours (based on the weight at a maximum dose of 10 mg per day). In the control group, the same placebo was used as a triple-blind.

Main outcome variables

Nausea and vomiting caused by chemotherapy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150119020715N6**

Registration date: **2018-06-23, 1397/04/02**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-23, 1397/04/02**

Update count: **0**

Registration date

2018-06-23, 1397/04/02

Registrant information

Name

Aziz Eghbali

Name of organization / entity

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Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-21, 1397/02/31

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation the Effect of Olanzapine on the Nausea and Vomiting Induced by Chemotherapy in Children with Malignancy.

Public title
The Effect of an Oral Medicine on Nausea and Vomiting Caused by Chemotherapy in Children With Cancer.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Children aged 5 to 15 years of age who have recently diagnosed as malignancy Indication of chemotherapy, based on assessment, diagnosis and approval by physician On the first day of chemotherapy, they should have a RAS score more than 20.
Exclusion criteria:
 Diseases that triggers the nausea and vomiting Inability to express the severity of nausea and vomiting Patients who has not satisfied with the study Olanzapine drug complications

Age
From **5 years** old to **15 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to randomization we will use the block method, based on this, two lists of patients are provided and each list is placed in one of the groups.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this study, patient , the statistical analyst and physician are blind for study group. In order to blind the patient, two lists are provided and based on the number of patient admission who is pairs or single, he were take on one of these lists. In order to blind the statistical analyst, information is generally presented in two groups, and he does not have any information about the intervention and control groups. Also, the physician have not any information about two groups, accordingly, use for patients medication or similar placebo.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Sardasht

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2018-02-10, 1396/11/21

Ethics committee reference number

IR.ARAKMU.REC.1396.288

Health conditions studied

1

Description of health condition studied

Nausea and vomiting

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

Primary outcomes

1

Description

Nausea and vomiting

Timepoint

Before starting chemotherapy, 24 hours after chemotherapy and 5 days after chemotherapy

Method of measurement

To evaluate the state of nausea and vomiting in patients, RAS criteria will be used to measure the state of nausea and vomiting in patients from 1 to 100.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 5 mg olanzapine tablets are used at

a dose of 0.1 mg / kg PO per 24 hours (based on the weight at a maximum dose of 10 mg per day).

Category

Treatment - Drugs

2

Description

Control group: Similar placebo in control group used as triple-blind

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Pediatrics, Amir Kabir Hospital

Full name of responsible person

Dr. Tahereh Bagherloo

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3819693345, Amir Kabir Hospital, Basij Square, Arak.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Aziz Eghbali

Position

Blood specialist and oncology

Latest degree

Subspecialist

Other areas of specialty/work

Blood and Oncology Diseases

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Person responsible for scientific inquiries

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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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