

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Assessing the effectiveness of olanzapine in treating nausea and vomiting caused by chemotherapy in children.

Protocol summary

Study aim

Evaluation of the Efficacy of Olanzapine in controlling chemotherapy-induced Nausea and Vomiting in Pediatrics

Design

A blinded randomized trial on 56 pediatric patients undergoing chemotherapy

Settings and conduct

56 patients undergoing chemotherapy and are hospitalized in Mofid Children's Hospital are randomly divided into two groups and the coded medicine package is delivered to them and finally the results will be collected.

Participants/Inclusion and exclusion criteria

Inclusion criteria :Pediatric patients aged from 1 year to 15 years undergoing chemotherapy treatment with moderate to severe nausea inducing regimen . exclusion criteria:heart failure or heart disease associated with the risk of arrhythmia, epilepsy, kidney or liver failure, mechanical ventilation.

Intervention groups

In one group patients receive olanzapine0.1mg/kg daily and in the other group patients receive placebo once daily as oral route.

Main outcome variables

occurrence of nausea and vomiting, oral intake tolerance, weight loss

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120415009475N14**

Registration date: **2023-10-11, 1402/07/19**

Registration timing: **prospective**

Last update: **2023-10-11, 1402/07/19**

Update count: **0**

Registration date

2023-10-11, 1402/07/19

Registrant information

Name

Bahador Mirrahimi

Name of organization / entity

Shahid Beheshti University of Medical Sciences,
Faculty of Pharmacy

Country

Iran (Islamic Republic of)

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+98 21 8820 0118

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-11-21, 1403/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effectiveness of olanzapine in treating nausea and vomiting caused by chemotherapy in children.

Public title

Olanzapine in pediatric chemotherapy induced nausea and vomiting in

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Pediatric patients undergoing chemotherapy with medications inducing moderate to severe nausea

Exclusion criteria:

Heart failure or heart disease associated with the risk of Arrhythmia. Epilepsy Kidney failure Liver failure Mechanical ventilation

Age

From **1 year** old to **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done based on the block randomization method with non-consequential codes generated by an online tool (sealedenvelope.com)

Blinding (investigator's opinion)

Double blinded

Blinding description

The medication and placebo will be in look-alike coded packages, and the codes based on the block randomization table will be provided to the researcher by a designated person via phone. At the end of the study, after organizing the data by the same person, the statistical expert will perform the analysis. Then, the code packet will be opened, and the final results will be reported.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

institutional ethics committee for Pharmacy, Nursing and midwifery schools

Street address

2nd floor, School of Nursing and Midwifery, Valiasr and Niayesh junction

City

Tehran

Province

Tehran

Postal code

1546815514

Approval date

2022-09-18, 1401/06/27

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1401.150

Health conditions studied

1

Description of health condition studied

Chemotherapy induced nausea and vomiting

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Occurrence of nausea and vomiting

Timepoint

Daily for 7 days

Method of measurement

Questionare

Secondary outcomes

1

Description

Oral intake tolerance

Timepoint

Daily for 7 days

Method of measurement

Questionare

2

Description

Weight loss

Timepoint

Daily for 7 days

Method of measurement

Weighing

Intervention groups

1

Description

Intervention group: Olanzapine dosing 0.1 milligrams per kilogram once daily at bedtime starting with chemotherapy for 3 days

Category

Treatment - Drugs

2

Description

Control group: Placebo with the same packing once daily at bedtime starting with chemotherapy for 3 dayschemotherapy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid children's Hospital

Full name of responsible person

Bahador Mirrahimi

Street address

Mofid Children's Hospital, Mirdamad Junction, Shariaty Ave.

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Email

mirrahimi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Seyed Ali Ziaee

Street address

3rd Floor, Faculty of medicine, Arabi Ave, Daneshjoo Blvd, Velenjak.

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1985717443.

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info@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Shahid Beheshti

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Negar Alibabae

Position

pharmacy student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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School of Pharmacy, Shahid Beheshti University of Medical Sciences, Niayesh junction, Valiasr Ave, Tehran, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Bahador Mirrahimi

Position

Asistant Profesor, Pharmacotherapy

Latest degree

Specialist

Other areas of specialty/work

Clinical pharmacy

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Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

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Position

Asistant Profesor, Pharmacotherapy

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

the primary outcome measure only

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

this will be only available to people working in academic institutions.

Under which criteria data/document could be used

Data will be available to be used for meta-analysis and systematic review.

From where data/document is obtainable

via an academic email to the corresponding author.

What processes are involved for a request to access data/document

requesting and reviewing the proposal abstract of the research and academic profile of the researcher (10 working days).

Comments