

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the efficacy and safety of adding olanzapine to the standard preventive regimen for chemotherapy- induced nausea and vomiting in children of 4-18 years of age, a Randomized Clinical Trial

Protocol summary

Study aim

To assess the effects of adding olanzapine to the standard prophylactic antiemetics (ondansetron and dexamethasone) used in children

Design

A double-blind, placebo-controlled, randomized clinical trial with parallel group

Settings and conduct

Patients hospitalized in the oncology division of Bouali Sina hospital undergoing chemotherapy with moderate to severe risk of emetogenicity will be included to receive interventions. All subjects will receive prophylactic antiemetics consist of serotonin antagonist (mainly granisetron), dexamethasone and metoclopramide . Half of them will receive daily olanzapine until the end of chemotherapy and the other half will receive placebo. Nausea and vomiting during the five days of chemotherapy and also metabolic effects including changes of fasting blood glucose and hyperlipidemia will be documented.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Age of 4 and 18 years 2- Cognitive abilities of 4 years old 3- Receive of chemotherapy with moderate to severe risk of nausea and vomiting
Exclusion criteria: 1- Brain tumor 2- Uncontrolled high blood pressure 3- Prior administration of anti-psychotics medications during 30 days before enrollment 4- History of prior malignant neuroleptic syndrome, cardiac arrhythmia or seizure 5- Hypersensitivity to olanzapine 6- Uncontrolled diabetes melitus 7- Inhibitors/Inducers of CYP1A2 enzymes

Intervention groups

First intervention group (Control): Usual prophylactic antiemetics consist of serotonin antagonist (mainly Granisetron), Dexamethasone and Metoclopramide along with placebo of Olanzapine
Second intervention group (Drug): Usual prophylactic antiemetics consist of

serotonin antagonist (mainly Granisetron), Dexamethasone and Metoclopramide along with Olanzapine 0.14 mg/kg

Main outcome variables

Nausea and vomiting during 24 hours after chemotherapy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090613002027N14**

Registration date: **2018-11-11, 1397/08/20**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-11, 1397/08/20**

Update count: **0**

Registration date

2018-11-11, 1397/08/20

Registrant information

Name

Ebrahim Salehifar

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 15 1311 6546

Email address

esalehifar@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-01, 1396/10/11

Expected recruitment end date

2019-01-01, 1397/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy and safety of adding olanzapine to the standard preventive regimen for chemotherapy- induced nausea and vomiting in children of 4-18 years of age, a Randomized Clinical Trial

Public title

Olanzapine as a medication to reduce nausea and vomiting following chemotherapy in children

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Cognitive abilities of 4 years old age Receiving chemotherapy medications with moderate to severe risk of emesis Age between 4 to 18 years old

Exclusion criteria:

Brain tumor Receive of any anti psychotics 30 days before enrollment Inhibitors/Inducers of CYP1A2 History of neuroleptic malignant syndrome History of seizure Sensitivity to olanzapine Cardiac arrhythmia History of uncontrolled diabetes mellitus

Age

From **4 years** old to **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **49**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation of patients into two groups will be conducted according to block randomization. The number of patients in each block will be 4 including two cases of olanzapine and two cases of placebo. The patients will be randomly allocated to drug or placebo within the block. Block randomization will be used to ensure that the equal number of patients will be distributed in each group of the study.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo will be prepared like as the active drug and placed in the envelopes labeled by a 5-digit unique number code for each patient. The physician and patient

will not be aware of the content of the envelope (e.g., drug or placebo). The study manager will keep the codes until the last of the study.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Institutional Review Board, Mazandaran School of Medical Sciences

Street address

Moallem Square

City

Sari

Province

Mazandaran

Postal code

4847193696

Approval date

2018-05-02, 1397/02/12

Ethics committee reference number

IR.MAZUMS.REC.1397.152

Health conditions studied**1****Description of health condition studied**

Palliative care

ICD-10 code

Z51.5

ICD-10 code description

Encounter for palliative care

Primary outcomes**1****Description**

Frequency of nausea in the first 5 days after chemotherapy

Timepoint

Baseline, 1, 2, 3, 4 and 5 days after intervention

Method of measurement

Interview with the patient

2**Description**

Frequency of vomiting in the first 5 days after chemotherapy

Timepoint

Baseline, 1, 2, 3, 4 and 5 days after intervention

Method of measurement

Interview with the patient

Secondary outcomes**1****Description**

Severity of Nausea during 5 days following chemotherapy

Timepoint

Baseline and days 1, 2, 3, 4 and 5 after intervention

Method of measurement

National Cancer Institute Common Terminology Criteria for Adverse Events version 4

2**Description**

Severity of Vomiting during 5 days following chemotherapy

Timepoint

Baseline and days 1, 2, 3, 4 and 5 after intervention

Method of measurement

National Cancer Institute Common Terminology Criteria for Adverse Events version 4

3**Description**

Fasting plasma glucose

Timepoint

Baseline and 5 days after intervention

Method of measurement

Laboratory Kit

4**Description**

Fasting triglyceride

Timepoint

Baseline and 5 days after intervention

Method of measurement

Laboratory Kit

5**Description**

Total Cholesterol

Timepoint

Baseline and 5 days after intervention

Method of measurement

Laboratory Kit

6**Description**

Aspartate aminotransferase

Timepoint

Baseline and 5 days after intervention

Method of measurement

Laboratory Kit

7**Description**

Alanine aminotransferase

Timepoint

Baseline and 5 days after intervention

Method of measurement

Laboratory Kit

8**Description**

Prolactine

Timepoint

Baseline and 5 days after intervention

Method of measurement

Laboratory Kit

Intervention groups**1****Description**

First intervention group (Control): consist of children age of 4-18 years old undergoing chemotherapy with moderate to high risk emetogenicity will receive usual prophylactic antiemetics consist of serotonin antagonist (mainly Granisetron), Dexamethasone and metoclopramide along with placebo of Olanzapine 5 mg daily until the end of chemotherapy.

Category

Treatment - Drugs

2**Description**

Second intervention group (Olanzapine) will receive Olanzapine (0.14 mg/kg) maximum 10 mg in addition to usual prophylactic antiemetics. Olanzapine dose will be rounded to the nearest 2.5 mg. If chemotherapy continues for more than 1 day, olanzapine will be repeated in the following days until the end of chemotherapy.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Bouali Sina Hospital, Sari

Full name of responsible person

Ebrahim Salehifar

Street address

Emam square, Pasdaran Boulevard

City

Sari

Province

Mazandaran
Postal code
4847191971
Phone
+98 11 3304 4018
Email
fkhdmona@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Majid Saeedi (Research and Technology Deputy)
Street address
Research and Technology Deputy, Moallem square,
Sari, Iran
City
Sari
Province
Mazandaran
Postal code
4847193696
Phone
+98 11 3325 7230
Email
majsaeeedi@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sari 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
Mazandaran University of Medical Sciences
Full name of responsible person
Ebrahim Salehifar
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy

Street address

Clinical Pharmacy Department, Faculty of Pharmacy,
KM 18 Khazar Abad Blvd, Khazar square

City

Sari

Province

Mazandaran

Postal code

4847193696

Phone

+98 15 1311 6546

Fax

Email

esalehifar@mazums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Ebrahim Salehifar
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Clinical Pharmacy Department, Faculty of Pharmacy,
KM 18 Khazar Abad Blvd, Khazar square
City
Sari
Province
Mazandaran
Postal code
4847193696
Phone
+98 15 1311 6546
Fax
Email
esalehifar@mazums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Ebrahim Salehifar
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Clinical Pharmacy Department, Faculty of Pharmacy,
KM 18 Khazar Abad Blvd, Khazar square
City
Sari

Province

Mazandaran

Postal code

4847193696

Phone

+98 15 1311 6546

Fax**Email**

esalehifar@mazums.ac.ir

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All demographic and clinical data will be shared after masking the identification of patients.

When the data will become available and for how long

For 5 years

To whom data/document is available

Public

Under which criteria data/document could be used

Each scientific analysis will be permitted.

From where data/document is obtainable

Ebrahim Salehifar

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

Request through Ebrahim Salehifar via an academic email that was confirmed by Research deputy of that institute

Comments