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 (ondansetrone 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)

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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 Choleterol
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 enf 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
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Province

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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
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Mazandaran
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4847193696
Phone
+98 11 3325 7230
Email
majsaeedi@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
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Person responsible for updating data

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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
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 Salehiar via an academic email that was confirmed by Research deputy of that institute
Comments