Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

The Effect of Aprepitant on Chemo-Induced Nausea and Vomiting in Children with Cancer

Protocol summary

Summary

Objectives: Nausea and vomiting are one of the most common and important complications in children who treated with chemotherapy drugs. The aim of this study was to evaluate the effect of apripitate on chemotherapy-induced nausea and vomiting in children with cancer who referred to Amirkabir Arak Hospital.
Design: This is a triangular clinical trial study performed on 30 children with malignancy referring to the Amirkabir Arak Hospital, which is undergoing chemotherapy.
Setting and conduct: After completing the consent form, a questionnaire and a checklist of necessary interventions are performed and the severity of nausea is determined by a Visual Analogue Scale of 0-100 millimeter. After completing the study, all statistical analyzes are performed using SPSS 21 software.
Participants including major eligibility criteria: Patients with chemotherapy malignancies aged 5 to 18 years of age who had no nausea due to other illness (at least 20 Visual Analogue Scale) and healthy eyesight entered the study group, but patients with severe manifestations of epipedan complications or the ability to determine Visual Analogue Scale are excluded from the study.
Intervention: Each patient receives the same for an hour before the first course of 40 mg / kg body weight chemotherapy in the form of a single dose of granisetron to a maximum dose of 3 mg per dose plus placebo on days 2 and 3, then the same in the second course of chemotherapy with the same chemotherapy regimen, in addition to granisetron to prevent nausea and vomiting, 125 mg of apripitant for patients 12 to 18 years of age and 3 mg per kg of body weight (eventually up to 125 mg) for ages 5 to 12 years on the first day and 80 mg for children 12 to 18 years and 2 mg per kg body weight (ultimately up to 80 mg) for age 5 to 12 years will receive in the second and third days. Main outcome measures: nausea and vomiting.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017080520715N3**
Registration date: **2017-09-05, 1396/06/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-09-05, 1396/06/14

Registrant information

Name
Aziz Eghbali
Name of organization / entity
دانشگاه علوم پزشکی اراک
Country
Iran (Islamic Republic of)
Phone
+98 86 3465 5314
Email address
dr.eghbali@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Effect of Aprepitant on Chemo-Induced Nausea and Vomiting in Children with Cancer

Public title
Clinical Trial Study of the Effect of Apripitant Drug on Nausea and Vomiting Due to Chemotherapy in Children

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: Patients with malignancies who was under chemotherapy with 5 to 18 years of age; non-nausea due to illness with the approval of the physician; presence of a healthy vision; attending the first day of chemotherapy and nausea severity; minimum score of 20 From VAS mm100 (visual analogue scale). Exclusion criteria: Severe manifestations of complications of the epiphyte including fever, severe infection, tinnitus, deep vein thrombosis, severe digestive problems, etc; failure of the patient to determine the severity of nausea based on the instructions.

Age
From **5 years** old to **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

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
3848176941, Arak University of Medical Sciences, Sardasht, Arak, Iran

City
Arak

Postal code

Approval date
2017-05-22, 1396/03/01

Ethics committee reference number
IR.ARAKMU.REC.1396.46

Health conditions studied

1

Description of health condition studied
nausea and vomiting

ICD-10 code
P54.0

ICD-10 code description
Nausea and vomiting of children

Primary outcomes

1

Description
Nausea and vomiting

Timepoint
1, 2nd and 3rd days

Method of measurement
Recorded in checklist

Secondary outcomes

empty

Intervention groups

1

Description
Each patient receives the same for an hour before the first course of 40 mg/kg body weight chemotherapy in the form of a single dose of granisetron to a maximum dose of 3 mg per dose plus placebo on days 2 and 3, then the same in the second course of chemotherapy with the same chemotherapy regimen, in addition to granisetron to prevent nausea and vomiting, 125 mg of apripitant for patients 12 to 18 years of age and 3 mg per kg of body weight (eventually up to 125 mg) for ages 5 to 12 years on the first day and 80 mg for children 12 to 18 years and 2 mg per kg body weight (ultimately up to 80 mg) for age 5 to 12 years will receive in the second and third days. In the control group, similar placebo was used.

Category
Treatment - Drugs

2

Description
In the control group, similar placebo was used.

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Pediatrics, Amir Kabir Hospital
Full name of responsible person
Aziz Eghbali
Street address
3819693345, Amir Kabir Hospital, Basij Square, Arak, Iran
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Arak University of Medical Sciences
Full name of responsible person
Ali Arash Anoushirvani
Street address
3819693345, Vice Chancellor for Research, Arak University of Medical Sciences, Sardasht, Arak, Iran
City
Arak
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, Arak University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Amir Kabir Hospital of Arak city
Full name of responsible person
Aziz Eghbali
Position
Assistant Professor of Pediatric Nephrology
Other areas of specialty/work
Street address
3819693345, Amir-Kabir Hospital, Basij Square, Arak, Iran
City
Arak
Postal code
3819693345
Phone
+33 135075
Fax
Email
dr.eghbali@arakmu.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Assistant Professor of Pediatric Hematology
Full name of responsible person
Aziz Eghbali
Position
Blood specialist and oncology
Other areas of specialty/work
Street address
3819693345, Amir Kabir Hospital, Basij Square, Arak, Iran
City
Arak
Postal code
Phone
+98 918 525 1319
Fax
Email
dr.eghbali@arakmu.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Assistant Professor of Pediatric Hematology
Full name of responsible person
Aziz Eghbali
Position
Blood specialist and oncology
Other areas of specialty/work
Street address
3819693345, Amir Kabir Hospital, Basij Square, Arak, Iran
City
Arak
Postal code
Phone
00
Fax
Email
dr.eghbali@arakmu.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty