

# 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 Aprepitant 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

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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**

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**

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#### 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**

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#### 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**

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#### 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*