

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Aug 2026

### The safety and efficacy of Aprepitant to prevent chemotherapy-induced nausea and vomiting in children with cancer

#### Protocol summary

##### Study aim

Determination of safety and efficacy of Aprepitant in preventing chemotherapy-induced nausea and vomiting in children with cancer

##### Design

A Quasi-experimental study, No randomization, No blinding, Phase 3 on 85 patients with cancer who candidate for chemotherapy , Enrolled between May 2020 and August 2020

##### Settings and conduct

A total of 85 children with cancer who are candidates for chemotherapy and referred to Aliasghar Children's Hospital receive Ondansetron thirty minutes before treatment intravenously at a dose of 0.15 mg / kg at one time. Then, in the next course of chemotherapy, the samples were taken orally 1 hour before the chemotherapy according to the patient's age for 3 days and once in each day. After the intervention, the number of vomitings and the amount of nausea are recorded based on the statements of the parents.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Parental consent , absence of nausea and vomiting for other reasons, No history of radiotherapy, No history of allergies, No history of other diseases. Non inclusion criteria: sensitivity to drugs under the study.

##### Intervention groups

A total of 85 children with cancer who are candidates for chemotherapy receive Ondansetron (produced by Exir Company, Iran) thirty minutes before treatment intravenously at a dose of 0.15 mg / kg at a time. Then, in the next course of chemotherapy, the samples take Aprepitant orally (produced by Abidi, Iran) 1 hour before the chemotherapy according to the patient's age, once a day for 3 days.

##### Main outcome variables

Rate of nausea and vomiting

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200819048455N1**

Registration date: **2020-09-13, 1399/06/23**

Registration timing: **retrospective**

Last update: **2020-09-13, 1399/06/23**

Update count: **0**

##### Registration date

2020-09-13, 1399/06/23

##### Registrant information

##### Name

Masoumeh Jafari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2304 6253

##### Email address

bahoush.gr@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-30, 1399/03/10

##### Expected recruitment end date

2020-08-31, 1399/06/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The safety and efficacy of Aprepitant to prevent chemotherapy-induced nausea and vomiting in children with cancer

IR.IUMS.FMD.REC.1399.146

## Public title

The safety and efficacy of Aprepitant to the prevention of chemotherapy-induced nausea and vomiting

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Parental consent  
Lack of nausea and vomiting for other reasons  
No history of radiotherapy  
No history of allergies  
No history of other disease

### Exclusion criteria:

Drug sensitivity

## Age

From **6 months** old to **17 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

No information

## Sample size

Target sample size: **85**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Iran University of Medical Sciences

##### Street address

Iran University of Medical Sciences; Shahid Hemmat Highway

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۳۴۹۶۱۴۵۳۵

## Approval date

2020-05-24, 1399/03/04

## Ethics committee reference number

## Health conditions studied

### 1

#### Description of health condition studied

Malignant cancer

#### ICD-10 code

C00-C97

#### ICD-10 code description

Malignant neoplasms

## Primary outcomes

### 1

#### Description

Nausea and vomiting

#### Timepoint

After the intervention for three days

#### Method of measurement

Parents' statements

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: A total of 85 children with cancer who are candidates for chemotherapy receive Ondansetron (produced by Exir Company, Iran) thirty minutes before treatment intravenously at a dose of 0.15 mg / kg at a time. Then, in the next course of chemotherapy, the samples take Aprepitant orally (produced by Abidi, Iran) 1 hour before the chemotherapy according to the patient's age (for ages 6 months to 12 years, the first day 3 mg/kg and on the second and third days 2 mg/kg, for ages 12 years and over, on the first day one capsule (125 mg) and on the second and third days, one 80 mg capsule), once a day for 3 days.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Aliaghar Children's Hospital

##### Full name of responsible person

Gholamreza Bahoush

##### Street address

Aliaghar Children's Hospital; No. 193, Vahid Dastgerdy avenue, Ayatollah Modares highway

**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1919816766  
**Phone**  
+98 21 2304 6253  
**Email**  
aach@iums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Abbas Motevalian  
**Street address**  
Iran University of Medical Sciences; Shahid Hemmat highway  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
۱۴۴۹۶۱۴۵۳۵  
**Phone**  
+98 21 86701  
**Email**  
motevalian.a@iums.ac.ir

#### Grant name

#### Grant code / Reference number

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

No

#### Title of funding source

Iran 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**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Masoumeh Jafari  
**Position**  
fellow  
**Latest degree**

Specialist

#### Other areas of specialty/work

Pediatrics

#### Street address

Aliaghar Children's Hospital; No. 193, Vahid Dastgerdy avenue, Ayatollah Modares highway

#### City

Tehran

#### Province

Tehran

#### Postal code

1919816766

#### Phone

+98 21 2304 6253

#### Email

dr.masoumeh.jafari@gmail.com

## Person responsible for scientific inquiries

#### Contact

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Gholamreza Bahoush

#### Position

Associate professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Hematology

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#### Province

Tehran

#### Postal code

1919816766

#### Phone

+98 21 2304 6253

#### Email

grbahoush1968@gmail.com

## Person responsible for updating data

#### Contact

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Gholamreza Bahoush

#### Position

Associate professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Hematology

#### Street address

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**Province**

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**Postal code**

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**Phone**

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**Email**

grbahoush1968@gmail.com

**Sharing plan**

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

Undecided - It is not yet known if there will be a plan to

make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to  
make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to  
make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable