Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Efficacy and safety of Aprepitant in prevention of chemotherapy induced nausea and vomiting in oncologic patients of Mofid children’s hospital

Protocol summary

Study aim

The efficacy and safety of Aprepitant in the prevention of chemotherapy-induced nausea and vomiting in pediatric oncology patients are useful.

Design

This double-blind and clinical trial .30 patients who are candidate for chemotherapy at Mofid Hospital in Tehran. We will divide patients in 4 groups by simple randomization. Groups are parallel.

Settings and conduct

This double-blind and clinical trial .This double-blind and clinical trial .30 patients who are candidate for chemotherapy at Mofid Hospital in Tehran.The patients are divided into 2 groups by simple randomization with envelopes.The study is double-blind.Outcome elevator and analyzer and participant are blind (double blind).

Participants/Inclusion and exclusion criteria

Inclusion criteria:age between 6 month to 17 years, proven malignancy, chemotherapy regimen with moderate to severe nausea, lack of nausea and vomiting 24 hours before starting chemotherapy, lack of known long QT syndrome, lack of abdominal and pelvic radiation therapy over the past week, no active infection or any uncontrolled disease associated with malignancy, absence of corticosteroids starting 72 hours prior to chemotherapy for any reason, lack of Benzodiazepine or opioid for 48 hours Exclusion criteria:Sensitivity to the drugs used, dissatisfaction

Intervention groups

Intervention group:We treat patients with 3 milligram in kilogram(maximum 120 milligram) Aprepitant and 0/15 milligram in kilogram ondansetron on the first day 5 minutes before chemotherapy and they received 2 milligram in kilogram (80 milligram) Aprepitant in the next 2 days. The control group will receive placebo of the same form and the same amount of Aprepitant.

Main outcome variables

Nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200204046377N1**
Registration date: **2020-04-03, 1399/01/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-03, 1399/01/15**
Update count: **0**

Registration date

2020-04-03, 1399/01/15

Registrant information

Name

Parastou Mollaei Tavana

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8823 3881

Email address

dr_p1984@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-07-05, 1399/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and safety of Aprepitant in prevention of chemotherapy induced nausea and vomiting in oncologic patients of Mofid children’s hospital

Public title
Evaluation of the efficacy of Aprepitant in vomiting of children with cancer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
age between 6 month to 17 years Proven malignancy Chemotherapy regimen with moderate to severe nausea Lack of nausea and vomiting 24 hours before starting chemotherapy Lack of known long QT syndrome Lack of abdominal and pelvic radiation therapy over the past week No active infection or any uncontrolled disease associated with malignancy Absence of corticosteroids starting 72 hours prior to chemotherapy for any reason Lack of Benzodiazepine or opioid for 48 hours
Exclusion criteria:
Sensitivity to the drugs used Dissatisfaction
Age
From **6 months** old to **17 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple individual randomization with randomization with envelopes in 4 groups A and B. In this method, we selected a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is clinical trial.Outcome elevator and analyzer and participant are blind (double blind).Outcome elevator and analyzer and participant don't aware from grouping.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Institute of Child Health-Shahid Beheshti University of Medical Sciences
Street address
Unit 42,Block 5,Negin complex,North Haji Pour Amir Ave,Sazmane Ab Blvd,Sheykh Fazlolah Freeway
City
Tehran
Province
Tehran
Postal code
1454653916
Approval date
2019-05-30, 1398/03/09
Ethics committee reference number
IR.SBMU.RICH.REC.1398.008

Health conditions studied

1

Description of health condition studied
Malignant cancer
ICD-10 code
D70.1
ICD-10 code description
Agranulocytosis secondary to cancer chemotherapy

Primary outcomes

1

Description
Nausea and vomiting
Timepoint
After the intervention for two days
Method of measurement
Appendix link table

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:We treat patients with 3 milligram in kilogram(maximum 120 milligram) Aprepitant and 0/15 milligram in kilogram ondansetron on the first day 5 minutes before chemotherapy and they received 2 milligram in kilogram (80 milligram) Aprepitant in the

next 2 days

Category

Treatment - Drugs

2

Description

Control group: The control group will receive placebo of the same form and the same amount of Aprepitant.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric congenital hematologic disorders research Center

Full name of responsible person

Fatemeh Malek

Street address

Mofid children hospital, Shariati Av

City

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Province

Tehran

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15468-15514

Phone

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Email

pchd@sbmu.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fatemeh Malek

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Others

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

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Other areas of specialty/work

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Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Parastoo Mollaei Tavana
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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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
When we publish article in journal
When the data will become available and for how long
After the article is published
To whom data/document is available
Researcher in university
Under which criteria data/document could be used
If there are additional questions
From where data/document is obtainable
Dr Fatemeh Malek
What processes are involved for a request to access data/document
They have to write letters to the professors and the university
Comments