Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 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

Tehran

Province

Tehran

Postal code

15468-15514

Phone

+98 21 3333 0006

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

Street address

Mofid children hospital, Shariati Av

City

Tehran

Province

Tehran

Postal code

15468-15514

Phone

+98 21 2290 5368

Email

zarghi@sbmu.ac.ir

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

Street address

Mofid children hospital, Shariati Av

City

Tehran

Province

Tehran

Postal code

15468-15514

Phone

+98 21 2290 5638

Email

fmalek7721@gmail.com

Person responsible for scientific 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

Street address

Mofid children hospital, Shariati Av

City

Tehran

Province

Tehran

Postal code

15468-15514

Phone
+98 21 2290 5638
Email
fmalek7721@gmail.com

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
Street address
Mofid children hospital, Shariati Av
City
Tehran
Province
Tehran
Postal code
15468-15514
Phone
+98 21 2226 5488
Email
dr_p1984@yahoo.com

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