Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation of anti-emetic efficacy of Aprepitant in patients undergo hematopoitic stem cell transplantation

Protocol summary

Summary

Since high-dosage chemotherapy and stem cell transplantation have become important in the treatment of many malignancies, and these regimens are often associated with symptoms of nausea and vomiting, Appropriate and effective control of this complication is an important step in improving the nutritional quality of these patients. With conventional anti emetic treatments patients who receive high-dose chemotherapy suffer from particular delayed nausea and vomiting which emphasis on necessity of new anti-emetic methods. In this study a group of 40 patients and a matched control group (40 patients)who undergo stem cell transplantation in Taleghani bone marrow transplantation center will be included. Patients in control group will receive conventional anti emetic therapy (dexamethasone 8 mg IV daily and Grarisetron1.5 mg bid IV up to third day post chemotherapy) and the same therapy with Aprepitant 120 mg PO first day and 80 mg po on the second and third days of chemotherapy) in study group. The rate of early and late nausea, vomiting, possible side effects and complications will be evaluated .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107026930N1**
Registration date: **2012-08-14, 1391/05/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-08-14, 1391/05/24

Registrant information

Name

Mahshid Mehdizadeh

Name of organization / entity

Shahid Beheshti university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2303 1372

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mehdizadeh@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2012-05-21, 1391/03/01

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of anti-emetic efficacy of Aprepitant in patients undergo hematopoitic stem cell transplantation

Public title

Evaluation of anti-emetic efficacy of Aprepitant in patients undergo hematopoitic stem cell transplantation in a teaching hospital

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: patients who undergo autologus bone marrow transplantation. Exclusion criteria: severe hepatic and renal failure during drug administration; hypersensitivity to the drug.

Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Pharmaceutical Sciences Research Center
Street address
No 10, Shams alley, Vali-e-asr ave
City
Tehran
Postal code
Approval date
2011-05-15, 1390/02/25
Ethics committee reference number
100

Health conditions studied

1

Description of health condition studied
Autologous bone marrow transplantation
ICD-10 code
Z94.8
ICD-10 code description
Other transplanted organ and tissue status

2

Description of health condition studied
emesis
ICD-10 code
K92.0
ICD-10 code description
Haematemesis

Primary outcomes

1

Description
The patient's nutritional status
Timepoint
5 days prior to the intervention until after patient discharge
Method of measurement
Ask the patient

2

Description
The need for tpn
Timepoint
5 days prior to the intervention until after patient discharge
Method of measurement
Recorded in the file

3

Description
Number of vomiting
Timepoint
5 days prior to the intervention until after patient discharge
Method of measurement
Ask the patient - the nurse reported

4

Description
Nausea
Timepoint
5 days prior to the intervention until after patient discharge
Method of measurement
Ask the patient

Secondary outcomes

1

Description
Constipation
Timepoint
5 days prior to the intervention until after patient discharge
Method of measurement
Ask the patient

2

Description
The number of cases disposed
Timepoint
5 days prior to the intervention until after patient discharge
Method of measurement
Ask the patient

3

Description
Headache
Timepoint
5 days prior to the intervention until after patient discharge
Method of measurement
Ask the patient

4

Description
Diarrhea
Timepoint
5 days prior to the intervention until after patient discharge
Method of measurement
Ask the patient

5

Description
fever
Timepoint
5 days prior to the intervention until after patient discharge
Method of measurement
By Digital Thermometers

6

Description
hiccup
Timepoint
5 days prior to the intervention until after patient discharge
Method of measurement
Ask the patient

7

Description
Anorexia
Timepoint
5 days prior to the intervention until after patient discharge
Method of measurement
Ask the patient

8

Description
Seizure
Timepoint
5 days prior to the intervention until after patient discharge
Method of measurement
Ask the patient

9

Description
Mucositis
Timepoint
5 days prior to the intervention until after patient discharge
Method of measurement
Examination

10

Description
Alkaline phosphatase levels
Timepoint
5 days prior to the intervention until after patient discharge
Method of measurement
Laboratory measurement

11

Description
Amylase levels
Timepoint
5 days prior to the intervention until after patient discharge
Method of measurement
Laboratory measurement

12

Description
The rate of bilirubin
Timepoint
5 days prior to the intervention until after patient discharge
Method of measurement
Laboratory measurement

13

Description
Transaminase levels
Timepoint
5 days prior to the intervention until after patient discharge
Method of measurement
Laboratory measurement

14

Description
Blood glucose
Timepoint
5 days prior to the intervention until after patient discharge
Method of measurement
Laboratory measurement

15

Description
Creatinine levels
Timepoint
5 days prior to the intervention until after patient discharge

Method of measurement
Laboratory measurement

16

Description
The amount of calcium
Timepoint
5 days prior to the intervention until after patient discharge
Method of measurement
Laboratory measurement

17

Description
Magnesium levels
Timepoint
5 days prior to the intervention until after patient discharge
Method of measurement
Laboratory measurement

18

Description
Occurrence SoS
Timepoint
5 days prior to the intervention until after patient discharge
Method of measurement
Examination

Intervention groups

1

Description
Intervention group: dexamethasone 8 mg IV daily Grarisetron1.5 mg bid IV Aprepitnt slow infusion (120 mg first day - the second and third days of 80 mg (po)
Category
Treatment - Drugs

2

Description
Control Group: Granisetron 1.5 mg bid IV dexamethasone 8 mg IV daily,
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
BMT unit of Taleghani hospital
Full name of responsible person
Dr. Mahshid Mehdizadeh
Street address
Taleghani hospital, next to Shahid Beheshti university of medical scinces, Evin
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Seyyed Amir Mohammad Mortazavian
Street address
Shahid Beheshti University of Medical Sciences, Evin
City
Tehran
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, Shahid Beheshti 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
Shahid Beheshti university of medical scinces
Full name of responsible person
Dr. Mahshid Mehdizadeh
Position
preceptor
Other areas of specialty/work
Street address
Taleghani BMT center, Taleghani hospital, Evin
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Mahshid Mehdizadeh

Position
Associate Professor

Other areas of specialty/work

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Taleghani BMT center, Taleghani hospital, next to Shahid Beheshti university of medical scinces, Evin

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Person responsible for updating data

Contact

Name of organization / entity
Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences

Full name of responsible person
Alireza Ghadirifard

Position

Other areas of specialty/work

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Phone
+98 21 8814 2028

Fax

Email
arghadirifard@gmail.com

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