

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation of anti-emetic efficacy of Aprepitant in patients undergo hematopoietic 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 Grisetron1.5 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)

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+98 21 2303 1372

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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 hematopoietic stem cell transplantation

Public title

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

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: patients who undergo autologous 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
 Granisetron 1.5 mg bid IV Aprepitant 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 sciences, 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 sciences

Full name of responsible person

Dr. Mahshid Mehdizadeh

Position

preceptor

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Associate Professor

Other areas of specialty/work**Street address**

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Web page address**Full name of responsible person**

Alireza Ghadirifard

Position**Other areas of specialty/work****Street address****City**

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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

Person responsible for updating data

Contact

Name of organization / entity

Faculty of Pharmacy, Shahid Beheshti University of
Medical Sciences