Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The comparison of effects of Filgrastim and Peg-Filgrastim in neutropenic patients

Protocol summary

Summary

The aim of this study is to compare the efficacy of two different drugs in children with neutropenia. Patients with less than 16 years and neutropenia due to leukemia or solid tumor refer to Ali Asghar Hospital blood clinic and department will be enrolled. The patients will be categorized based on the underlying disease to three categories: patients with leukemia and neutropenia follow by chemotherapy, patients with leukemia and neutropenia follow by infection, patients with solid tumor and neutropenia follow by chemotherapy. 11 patients will be selected consecutively from each group and will be treated with filgrastim in the first round of chemotherapy. The same patients will be treated with the pegfilgrastim in next period. Thus, patients in both groups will be same and equal to 33. The filgrastim and pegfilgrastim will injected subcutaneously with a 5-10 µg/kg/day dose to 7 days and a 100 µg/kg as a single dose, respectively. We will check absolute neutrophil count 7 days after the last injection in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205279875N1**
Registration date: **2014-03-01, 1392/12/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-03-01, 1392/12/10

Registrant information

Name

saeed yousefian

Name of organization / entity

ali asghar hosp.

Country

Iran (Islamic Republic of)

Phone

+98 21 2304 6411

Email address

s_yousefian@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Cinnagen Drug Corporation

Expected recruitment start date

2012-09-01, 1391/06/11

Expected recruitment end date

2014-02-01, 1392/11/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of effects of Filgrastim and Peg-Filgrastim in neutropenic patients

Public title

The comparison of effects of two drugs in neutropenic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:Patients with leukemia or solid tumor; Neutropenia due to infection or chemotherapy Exclusion criteria: Patients with drug reaction to investigation drugs; Failure to refer the patients to follow up.

Age

From **1 year** old to **16 years** old

Gender

Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **66**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features
Patients, drug injectors and physicians were aware of the drug is injected. There was no possibility blinding of the groups due to difference in drug injection days. Groups participating in the study were three different groups include 11 subjects were selected from each group. The randomizing in our study is unenforceable. In this study, 33 patients were enrolled in three different groups according to underlying disease. The patients at two different times under two different treatment and self control groups were considered as individual. Thus overall sample size in this study is equal to 66.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee, Tehran University of Medical Sciences
Street address
Poursina Ave,16th Azar Ave
City
Tehran
Postal code
Approval date
2012-05-12, 1391/02/23
Ethics committee reference number
91.2134.130.د

Health conditions studied

1

Description of health condition studied
Neutropenia
ICD-10 code
D70
ICD-10 code description
Neutropenia

Primary outcomes

1

Description
Absolute Neutrophil Count
Timepoint
A week followig end of treatment
Method of measurement
Laboratory

Secondary outcomes

1

Description
Drug side effect
Timepoint
7 days after treatment
Method of measurement
Physical Examination

Intervention groups

1

Description
Filgrastim, subcutaneously, 5-10 µg/kg, daily, to 7 days
Category
Treatment - Drugs

2

Description
Pegfilgrastim, Ampule subcutaneously,100 µg/kg as a single dose
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali Asghar Hospital
Full name of responsible person
Saeed Yousefian
Street address
Zafar Avenue, Modares Avenue
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Cinnagen Drug Corporation
Full name of responsible person

Saeed Yousefian
Street address
5th floor, No 56, Azimi Ave, 1st Phase, Ekbatan Town
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Cinnagen Drug Corporation
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
Ali Asghar Hospital
Full name of responsible person
Saeed Yousefian
Position
Fellowship of Pediatric Hematology and Oncology
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Person responsible for updating data

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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