

# 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**

91.2134.130.3

**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 following 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

**Other areas of specialty/work**

**Street address**

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**Web page address**

## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*