

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative study of filgrastim and pegfilgrastim effect in the treatment of fever and neutropenia in patients with leukemia

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

#### Study aim

Comparative study of filgrastim and pegfilgrastim effect in the treatment of fever and neutropenia in patients with leukemia

Last update: **2017-12-22, 1396/10/01**

Update count: **0**

#### Registration date

2017-12-22, 1396/10/01

#### Design

In this study, 120 patients with leukemia referred to Mohammad Kermanshahi Hospital in Kermanshah city who are eligible for inclusion in the study will be selected conveniently and randomly will be assigned into two intervention groups and each participant will be assigned a code.

#### Registrant information

##### Name

Feizollah Foroughi

##### Name of organization / entity

kermanshah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 1821 4653

##### Email address

fforoughi@kums.ac.ir

#### Settings and conduct

This study will be conducted as a single blind clinical trial, by a research assistant at the Mohammad Kermanshahi Hospital . In this way that participants do not know which intervention group will be assigned to and which medication they will receive.

#### Recruitment status

**Recruitment complete**

#### Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients suffering from leukemia who have fever and neutropenia (NAC less than 1500)

Exclusion criteria: Neutropenic patients other than leukemia; patients who have not received the full course of treatment

#### Expected recruitment start date

2017-09-01, 1396/06/10

#### Expected recruitment end date

2017-12-31, 1396/10/10

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Intervention groups

The first intervention group will receive ten micro gram per kilogram filgrastim for three days for treatment of neutropenia , and the second intervention group will receive one tenth micro gram per kilogram of pegfilgrastim in single dose form

#### Scientific title

Comparative study of filgrastim and pegfilgrastim effect in the treatment of fever and neutropenia in patients with leukemia

#### Main outcome variables

Fever and neutropenic levels

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130812014333N80**

Registration date: **2017-12-22, 1396/10/01**

**Public title**

The effect of filgrastim and pegfilgrastim in the treatment of fever and immune deficiency

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with leukemia, suffering from fever and neutropenia (NAC less than 1500)

**Exclusion criteria:**

Neutropenic patients other than leukemia patients who have not received the full course of treatment

**Age**

From **1 year** old to **10 years** old

**Gender**

Both

**Phase**

1-2

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization will be done by coin tossing (throwing a coin).

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In this study, participants will not be informed about which intervention group they will be assigned to.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Kermanshah University of Medical Sciences

**Street address**

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Blvd

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Approval date**

2017-02-26, 1395/12/08

**Ethics committee reference number**

KUMS.REC.1395.764

**Health conditions studied****1****Description of health condition studied**

Ischemic stroke

**ICD-10 code**

I63

**ICD-10 code description**

Cerebral infarction

**Primary outcomes****1****Description**

Fever

**Timepoint**

At the beginning of the study, every other day until fever is stopped

**Method of measurement**

Using the Thermometer

**2****Description**

Neutropenia

**Timepoint**

At the beginning of the study, every other day until the ANC reaches over 1500

**Method of measurement**

Based on laboratory kits and based on the results of blood tests

**Secondary outcomes**

empty

**Intervention groups****1****Description**

The first intervention group will receive ten micro gram per kilogram Filgrastim (produced by Cinnagen pharmaceutical company) in the form of intramuscular injection for three days

**Category**

Treatment - Drugs

**2****Description**

Intervention group 2 will receive 0.1 micro gram per kilogram Pegfilgrastim (produced by Cinnagen pharmaceutical company) in a single dose intramuscular injection

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Mohammad Kermanshahi Hospital

**Full name of responsible person**

Dr. Mohamad hosseyn Rasoli

**Street address**Mohammad Kermanshahi Hospital, Helala Ahmar  
Crossroads**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 3427 6301

**Email**

M-Rcolpayecani@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**Vice chancellor for research, Kermanshah University  
of Medical Sciences**Full name of responsible person**

Koroush Hamzehee

**Street address**Vice Chancellor for Research Affairs, Kermanshah  
University of Medical Sciences, Building No.2, Shahid  
Beheshti Blvd**City**

Kermanshah

**Province**

Kermanshah

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6715847141

**Phone**

+98 83 3836 0014

**Email**

fnajafi@kums.ac.ir

**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, Kermanshah 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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Hosseyn Rasoli

**Position**

Resident in training, children's specialty

**Latest degree**

Medical doctor

**Other areas of specialty/work****Street address**Mohammad Kermanshahi Hospital, Helala Ahmar  
Crossroads**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 3025 0285

**Fax****Email**

m.rasoli@yahoo.com

**Web page address****Person responsible for scientific  
inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Mohammadreza Golpaygani

**Position**

Subspecialist in Blood and oncology

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Hematology

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**Email**

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad hosseyn Rasoli

**Position**

Resident in training, children's specialty

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

**Street address**

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**Postal code**

6715847141

**Phone**

+98 83 3025 0285

**Fax****Email**

m.rasoli@yahoo.com

**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The main result of the study will be shared.

**When the data will become available and for how long**

3 months

**To whom data/document is available**

If requested, results will be made available to other academic researchers

**Under which criteria data/document could be used**

Collected data is confidential and will not be shared with anyone else

**From where data/document is obtainable**

To receive the documentation, email send for update manager

**What processes are involved for a request to access data/document**

In a 15-day period, the documents will be sent e-mail

**Comments**