Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

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

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.

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.

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

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

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**
Registration timing: **registered_while_recruiting**

Last update: **2017-12-22, 1396/10/01**
Update count: **0**

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

Registrant information

Name
Feizollah Foroughi

Name of organization / entity
kermanshah University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Vice chancellor for research, Kermanshah University of Medical Sciences

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

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

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
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Mohammad Kermanshahi Hospital, Helala Ahmar Crossroads
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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
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Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Blvd
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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
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Other areas of specialty/work
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Person responsible for updating data

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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