Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

A single dose of pegfilgrastim compared with daily filgrastim for supporting neutrophil recovery in patients with acute myeloid leukemia after chemotherapy

Protocol summary

Study aim
Determination of the Short-acting G-CSF Method and Long acting PEG_GCSF method on the neutrophils count in patients after chemotherapy and there complications

Design
In a clinical trial, patients were assigned to study groups using randomized six-block. The person who evaluated outcomes was not aware from the type of intervention.

Settings and conduct
This study was conducted at Kowsar Hospital, an academic hospital affiliated with the Semnan University of Medical Sciences and Health Services.

Participants/Inclusion and exclusion criteria
All patients between 15 to 65 years old with Acute myeloid leukemia who have received induction chemotherapy and went to remission enrolled in study after receiving high dose cytarabine and if patients have sepsis, excluded from study.

Intervention groups
Patients received a course induction chemotherapy (idarubicin 12 mg/m2 days 1–3, cytarabine 100 mg/m2 twice daily days 1–7). If complete remission was achieved, patients received one course of high-dose cytarabine consolidation therapy (3 g/m2 if aged <55 years, 2 g/m2 if aged ≥ 55 years). Then patients were randomly assigned to receive either tow intervention groups. In the first group, Filgrastim 5 µg/kg SC was administered daily beginning 24 hours after chemotherapy. In the second group Pegfilgrastim was administered as a single SC 6-mg dose approximately 24 hours after completing chemotherapy. Then complete blood cell count and differential and peripheral blood smear were performed for all patients and patients evaluated for outcomes and complications for up to 21 days.

Main outcome variables
Increasing of Neutrophil count

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151020024625N8**
Registration date: **2018-06-30, 1397/04/09**
Registration timing: **retrospective**

Last update: **2018-06-30, 1397/04/09**
Update count: **0**

Registration date
2018-06-30, 1397/04/09

Registrant information

Name
Mehrdad Zahmatkesh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 23 3343 7844

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mehrdadzahmatkesh@semums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-01-20, 1395/11/01

Expected recruitment end date
2018-01-20, 1396/10/30

Actual recruitment start date
2017-01-20, 1395/11/01

Actual recruitment end date
2018-04-20, 1397/01/31

Trial completion date
empty

Scientific title
A single dose of pegfilgrastim compared with daily filgrastim for supporting neutrophil recovery in patients with acute myeloid leukemia after chemotherapy

Public title
Pegfilgrastim compared with filgrastim in patients with acute myeloid leukemia after chemotherapy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who went to remission after induction chemotherapy.
Exclusion criteria:
Non remission Sepsis during or after chemotherapy
History of hypersensitivity reactions to E. coli-derived proteins and other drugs
Age
From **15 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **58**
Actual sample size reached: **58**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization by six block randomization
Blinding (investigator's opinion)
Single blinded
Blinding description
The person who evaluate outcome is unaware from type of intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Semnan University of Medical Sciences
Street address
Basidj Boulevard
City
Semnan
Province
Semnan
Postal code
3519899951
Approval date
2015-10-06, 1394/07/14
Ethics committee reference number
IR.SEMUMS.REC.1394.93

Health conditions studied

1

Description of health condition studied
Neutropenia
ICD-10 code
D72
ICD-10 code description
Other disorders of white blood cells

Primary outcomes

1

Description
Neutrophil count
Timepoint
Daily< up to 21 days after intervention
Method of measurement
Complete blood cell count and peripheral blood smear

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients received one or two course induction chemotherapy (idarubicin 12 mg/m2 days 1–3, cytarabine 100 mg/m2 twice daily days 1–7). If complete remission was achieved, patients received one course of high-dose cytarabine consolidation therapy (3 g/m2 if aged <55 years, 2 g/m2 if aged ≥ 55 years). Then, Filgrastim 5 µg/kg SC was administered daily beginning 24 hours after chemotherapy. Then complete blood cell count and differential and peripheral blood smear were performed for all patients and patients evaluated for outcomes and complications for up to 21 days.
Category
Treatment - Other

2

Description
Intervention group: Patients received a course induction chemotherapy (idarubicin 12 mg/m2 days 1–3, cytarabine 100 mg/m2 twice daily days 1–7). If complete remission was achieved, patients received one course of high-dose cytarabine consolidation therapy (3 g/m2 if aged <55 years, 2 g/m2 if aged ≥ 55 years). Then,

Pegfilgrastim was administered as a single SC 6-mg dose approximately 24 hours after completing chemotherapy. Then complete blood cell count and differential and peripheral blood smear were performed for all patients and patients evaluated for outcomes and complications for up to 21 days.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital, affiliated to Semnan Universities of Medical Sciences

Full name of responsible person

Farahnaz Ghahremanfard MD

Street address

Basidj Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Mohammad Reza Asgari

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Farahnaz Ghahremanfard MD

Position

Associte professor

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Farahnaz Ghahremanfard MD

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Mehrdad Zahmatkesh

Position
Research Expert

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available

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

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

Title and more details about the data/document
Data will publish as final report.

When the data will become available and for how long
After completing

To whom data/document is available
Researchers and Physicians

Under which criteria data/document could be used
For similar studies and clinical use

From where data/document is obtainable
Scientific responsible, Farahnaz Ghahremanfard MD

What processes are involved for a request to access data/document
Call contact or e.mail

Comments