

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 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/m<sup>2</sup> days 1-3, cytarabine 100 mg/m<sup>2</sup> twice daily days 1-7). If complete remission was achieved, patients received one course of high-dose cytarabine consolidation therapy (3 g/m<sup>2</sup> if aged <55 years, 2 g/m<sup>2</sup> if aged ≥ 55 years). Then patients were randomly assigned to receive either two 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)

##### Phone

+98 23 3343 7844

##### Email address

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

**City**

Semnan

**Province**

Semnan

**Postal code**

3519899951

**Phone**

+98 23 3142 2120

**Email**

f\_ghahremanfard@yahoo.ccm

**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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Semnan

**Province**

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+98 23 3345 1336

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sem.ums.res@gmail.com

**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**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Hematology

**Street address**

Basidj Boulevard

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**Postal code**

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

Semnan University of Medical Sciences

**Full name of responsible person**

Farahnaz Ghahremanfard MD

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Hematology

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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

**Street address**

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**Postal code**

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**Phone**

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**Email**

mehrdadzahmatkesh@semums.ac.ir

## 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**