

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of the effect of pegfilgrastim with filgrastim on the neutrophil count of cancer patients under chemotherapy, a randomization clinical trial.

#### Protocol summary

##### Study aim

Comparison of the effect of pegfilgrastim with filgrastim on the neutrophil count of cancer patients under chemotherapy.

##### Design

Clinical trial with 2 intervention group, randomised, parallel group, phase 3 on 60 patients, permuted blocks are used for randomization.

##### Settings and conduct

this clinical trial that will be performed in Kosar Semnan. At the beginning of the study, the demographic information of all patients and the primary CBC test are recorded in the data collection form. Patients are then randomly divided into two groups 1 and 2. Intervention group 1: Patients are in this group for a period of chemotherapy. For patients 24 hours after chemotherapy, 5 ug/kg of filgrastim is prescribed for 4 days. Intervention group 2: Patients are in this group for a period of chemotherapy. For patients 24 hours after chemotherapy, a single dose of 6 mg of pegfilgrastim is prescribed. Patients are followed up until the next round of chemotherapy, and before starting the next round of chemotherapy, the CBC test is retaken and recorded in the data collection form.

##### Participants/Inclusion and exclusion criteria

Having satisfaction, Age over 18 years, Chemotherapy in Omid ward of Kowsar hospital, History of at least 1 course of chemotherapy, Use myelosuppression chemotherapy drugs, Lack of allergy to pegfilgrastim and filgrastim, Absence of underlying diseases

##### Intervention groups

Intervention group 1: Patients are in this group for a period of chemotherapy. For patients 24 hours after chemotherapy, 5 ug/kg of filgrastim (brand name: Tinagrast, a product of Arya Tina Gene Pharmaceutical Company) is prescribed for 4 days. Intervention group 2: Patients are in this group for a period of chemotherapy.

For patients 24 hours after chemotherapy, a single dose of 6 mg of pegfilgrastim (brand name: Pagagen, a product of Sinagen Pharmaceutical Company) is prescribed.

##### Main outcome variables

Neutrophil count.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180119038433N3**

Registration date: **2020-09-26, 1399/07/05**

Registration timing: **prospective**

Last update: **2020-09-26, 1399/07/05**

Update count: **0**

##### Registration date

2020-09-26, 1399/07/05

##### Registrant information

##### Name

Amin Izadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3346 5228

##### Email address

aminizadi1374@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-10-22, 1399/08/01

##### Expected recruitment end date

2021-03-21, 1400/01/01  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Comparison of the effect of pegfilgrastim with filgrastim on the neutrophil count of cancer patients under chemotherapy, a randomization clinical trial.

**Public title**  
Comparison of the effect of pegfilgrastim with filgrastim on the neutrophil count of cancer patients under chemotherapy.

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Having satisfaction Age over 18 years Chemotherapy in Omid ward of Kowsar hospital History of at least 1 course of chemotherapy Use myelosuppression chemotherapy drugs Lack of allergy to pegfilgrastim and filgrastim Absence of underlying diseases  
**Exclusion criteria:**  
Patients with underlying disease Allergy to pegfilgrastim or filgrastim Severe fever and neutropenia in previous courses of chemotherapy Patients with advanced cancer Not consent to participate in the study

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Randomization is done by permutation block method. It is an individual randomization unit. In this study, 4 blocks are used that have six modes (P,P,F,F and P,F,P,F and P,F,F,P and F,P,F,P and F,F,P,P and F, P, P, F) occurs, when we write each state on a card. Due to the fact that the sample size is 60 people, the above cards are used 15 times with replacement. The cards are selected using a random number table. (P= Pegfilgrastim group, F= Filgerastim group)

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**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

Basij Blvd, Semnan, Iran

##### City

Semnan

##### Province

Semnan

##### Postal code

3514799442

#### Approval date

2020-08-25, 1399/06/04

#### Ethics committee reference number

IR.SEMUMS.REC.1399.160

## Health conditions studied

### 1

#### Description of health condition studied

Chemotherapy

#### ICD-10 code

Z51.1

#### ICD-10 code description

Encounter for antineoplastic chemotherapy and immunotherapy

## Primary outcomes

### 1

#### Description

Neutrophil count.

#### Timepoint

Before the intervention and before the next round of chemotherapy.

#### Method of measurement

Complete Blood cell count and Differential count.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients are in this group for a period of chemotherapy. For patients 24 hours after chemotherapy, 5 ug/kg of filgrastim (brand name: Tinagrast, a product of Arya Tina Gene Pharmaceutical

Company) is prescribed for 4 days.

**Category**

Treatment - Drugs

**2****Description**

Intervention group: Patients are in this group for a period of chemotherapy. For patients 24 hours after chemotherapy, a single dose of 6 mg of pegfilgrastim (brand name: Pagagen, a product of Sinagen Pharmaceutical Company) is prescribed.

**Category**

Treatment - Drugs

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

Kowsar hospital of Semnan

**Full name of responsible person**

Mohammad Amir Sarabi

**Street address**

Kowsar hospital, Amin Blvd.

**City**

Semnan

**Province**

Semnan

**Postal code**

3519899951

**Phone**

+98 23 3142 2001

**Email**

kosarhos@semums.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Parviz Kokhaei

**Street address**

Basij Blvd, Semnan, Iran

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**Province**

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p\_kokha@yahoo.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**

Mohammad Amir Sarabi

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Hematology

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

Semnan University of Medical Sciences

**Full name of responsible person**

Mohammad Amir Sarabi

**Position**

Assistant 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**

Mohammad Amir Sarabi

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Hematology

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**Province**

Semnan

**Postal code**

3519899951

**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**

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