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 pegfilrastim 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 pegfilrastim 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 Diffrential 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

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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

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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

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
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Semnan University of Medical Sciences
Full name of responsible person
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Position
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Subspecialist
Other areas of specialty/work
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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
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