Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Clinical trial of comparison between prophylactic effect of filgrastim and pegfilgrastim on neutropenia caused by chemotherapy of solid tumors in children

Protocol summary

Summary

The aim of this study is to compare the effect of Filgrastim and Pegfilgrastim in preventing chemotherapy induced neutropenia in children with solid tumors. Crossover study carried out in children who were admitted in oncology ward of Amirkabir Hospital. Inclusion criteria will be solid tumor confirmed by pathology, children less than 15 years and their parental consent. Exclusion criteria will be severe infection, Use of Corticosteroid, sensitivity to Filgrastim or Pegfilgrastim and lack of parental consent to continue participating in the study. Patients will be randomly divided into 3 groups of 30 and each group will be treated 24 hours after chemotherapy. The Filgrastim and Pegfilgrastim will injected subcutaneously with a 10 µg/kg/day dose and a 100 µg/kg as a single dose, respectively. Group one will be treated with a daily dose of Filgrastim in the first period and Pegfilgrastim in the second, separated by a washout period of at least 30 days. In contrast, the second group will be treated with a daily dose of Pegfilgrastim in the first period and Filgrastim in the other and the third group will be received no medication. Cell blood counts will be taken in the beginning and in the 3, 7, 14 days of the treatment. The side effects and duration of neutropenia and hospitalization due to adverse drug reactions as well as the delay in starting the next cycle of chemotherapy and chemotherapy dose reductions due to neutropenia and treatment costs will be recorded. Finally, collected data will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011131878N1**
Registration date: **2017-04-29, 1396/02/09**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2017-04-29, 1396/02/09

Registrant information

Name
Maryam Behtash
Name of organization / entity
Arak University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 936 620 8067
Email address
maryam.behtash@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2017-05-04, 1396/02/14

Expected recruitment end date

2017-10-06, 1396/07/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of comparison between prophylactic effect of filgrastim and pegfilgrastim on neutropenia caused by chemotherapy of solid tumors in children

Public title

The comparison of effects of two drugs in neutropenic patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Solid tumor confirmed by pathology; Children less than 15 years; Parental consent. Exclusion criteria: Severe infection; Use of Corticosteroid; Sensitivity to filgrastim or pegfilgrastim; Lack of parental consent to continue participating in the study.

Age
From **1 year** old to **15 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features
Patients will be placed randomly in three groups using random number table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee Arak University of Medical Sciences

Street address
Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak

City
Arak

Postal code
3814957558

Approval date
2016-12-12, 1395/09/22

Ethics committee reference number
IR.ARAKMU.REC.1395.312

Health conditions studied

1

Description of health condition studied
Neutropenia

ICD-10 code
D70

ICD-10 code description
Neutropenia

Primary outcomes

1

Description
Absolute Neutrophil Count

Timepoint
Before chemotherapy and the first, third, seventh and fourteenth day after Granulocyte Colony Stimulating Factor (GCSF) administration.

Method of measurement
Laboratory

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Group one will be treated with a daily dose of Filgrastim in the first period and Pegfilgrastim in the second, separated by a washout period of at least 30 days. The Filgrastim and Pegfilgrastim will injected subcutaneously with a 10 µg/kg/day dose and a 100 µg/kg as a single dose, respectively.

Category
Treatment - Drugs

2

Description
Intervention group 2: Group two will be treated with a daily dose of Pegfilgrastim in the first period and Filgrastim in the second, separated by a washout period of at least 30 days. The Filgrastim and Pegfilgrastim will injected subcutaneously with a 10 µg/kg/day dose and a 100 µg/kg as a single dose, respectively.

Category
Treatment - Drugs

3

Description
Control group: Third group will be received no medication.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Amir-Kabir Hospital
Full name of responsible person
Dr Aziz Eghbali
Street address
Amir-Kabir Hospital, Rah-Ahan Street, Arak
City
Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Arak University of Medical Sciences
Full name of responsible person
Dr Mohammad Rafiee
Street address
Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak
City
Arak
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, Arak University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Amir-Kabir Hospital
Full name of responsible person
Dr Aziz Eghbali
Position
Professor of Pediatric Hematology and Oncology
Other areas of specialty/work
Street address
Amir-Kabir Hospital, Rah-ahan ave, Arak
City
Arak
Postal code
3819691187
Phone
+98 86 3313 5075
Fax
+98 86 3313 5075
Email
aziz_eghbali@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Amir-Kabir Hospital
Full name of responsible person
Dr Aziz Eghbali
Position
Professor of Pediatric Hematology and Oncology
Other areas of specialty/work
Street address
Amir-Kabir Hospital, Rah-ahan ave, Arak
City
Arak
Postal code
3819691187
Phone
+98 86 3313 5075
Fax
+98 86 3313 5075
Email
aziz_eghbali@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Maryam Behtash
Position
Medical Student
Other areas of specialty/work
Street address
Arak University of Medical Science, Alamolhoda Ave.
City
Arak
Postal code
3814957558
Phone
+98 864173638
Fax
Email
y.behtash@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty