

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 be 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

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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

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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

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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

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**

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Full name of responsible person

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Position

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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