

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparative study of two doses of filgrastim (5 and 15 Microgram/ kg) on the absolute neutrophil count in children with cancer

Protocol summary

Study aim

Comparison of the effect of two doses of filgrastim (5 and 15 µg/kg) on absolute neutrophil counts in children with cancers

Design

clinical trial with two parallel, randomized and non-blind groups

Settings and conduct

Neutropenia patients admitted to Gorgan Taleghani Hospital oncology center who had inclusion/ exclusion criteria will assign to two groups by random allocation list. then by a checklist increasing rate of ANC, number of admission days, antibiotics & type of malignancy will be compared in two groups. Administration of antibiotics will be according to protocol, First, ceftriaxone and amikacin will be prescribed, If no response to treatment is given after 48 hours, vancomycin will be prescribed, if it does not respond again ceftriaxone will be changed to ceftazidime. for checking fever T chart is provided, also for blood components every 48 hours patients CBC are taken, if ANC > 1500 medication will be stopped.

Participants/Inclusion and exclusion criteria

inclusion criteria: patients with cancer associated with neutropenia; Parents informed consent; patients with absolute neutrophil count<1500 with one of the following items: 1.Neutropenia lasts for more than 7-10 days 2.Low blood pressure 3.Profound neutropenia 4.Sepsis 5.Pneumonia 6.fungal infections exclusion criteria: Patients with less than 1500 neutrophils while they have active leukemia or leukemia is not in the remission phase

Intervention groups

Group A will receive dose 5 and Group B 15 of the drug. Considering that the dose of 5 to 10 is used routinely in the therapeutic centers. Therefore, patients receiving the dose of 5 group A define as control group and patients receiving the dose of 15 group B as the intervention group

Main outcome variables

The absolute neutrophil count; number of hospitalization

days; number of days that patient received antibiotics; time taken to stop the fever

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180103038196N8**

Registration date: **2019-07-13, 1398/04/22**

Registration timing: **retrospective**

Last update: **2019-07-13, 1398/04/22**

Update count: **0**

Registration date

2019-07-13, 1398/04/22

Registrant information

Name

Amir Hossein Salimi Kordasiabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 912 361 5549

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of two doses of filgrastim (5 and 15 Microgram/ kg) on the absolute neutrophil count in children with cancer

Public title

Comparison of the effect of two doses of filgrastim in the treatment of neutropenia

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

patients with cancer associated with neutropenia
Parents' informed consent for their child's participation in the study patients with absolute neutrophil count<1500 with one of the following items: Neutropenia lasts for more than 7-10 days Low blood pressure Profound neutropenia Sepsis pneumonia fungal infections

Exclusion criteria:

Patients with less than 1500 neutrophils while they have active leukemia or their leukemia is not in the remission phase.

Age

To 14 years old

Gender

Both

Phase

2-3

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

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly allocated to one of the two groups A (5 Dose) or B (15 Dose). In such a way that drugs with doses of 5 and 15 will be prepared in similar packages, then, according to the sample size in each group, Using the Excel software in a column, a list of letters A and B will be created and in the next column a list of random numbers will be generated. And then the column of letters will be arranged based on the column of random numbers. then a sequence of random letters of A and B will be obtained. Assign the next column to the numbering, The number recorded against the letters A and B will be recorded on a package of the corresponding dose drug. and the Packages are provided to the therapist. Eligible patients will receive a package medication based on their order of referral, The name of the patient and the number on medication package will be included in a list and will be made available to the project executives.

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 Gorgan university of medical sciences

Street address

Golestan Medical University, 5th kilometer Gorgan-Sari Road-at the beginning of the Shastkola street, Gorgan

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2017-06-23, 1396/04/02

Ethics committee reference number

ir.goums.rec.1396.289

Health conditions studied**1****Description of health condition studied**

Neutropenia

ICD-10 code

D70

ICD-10 code description

Neutropenia

Primary outcomes**1****Description**

ANC increase rate

Timepoint

Each 48 hours will be done, and when the ANC is over 1500, the medication will be discontinued

Method of measurement

Study of CBC Elements

2**Description**

number of hospitalization days

Timepoint

Hospitalize duration

Method of measurement

from patient documents

3

Description

number of days that patient received antibiotics

Timepoint

Hospitalize duration

Method of measurement

from patient documents

4

Description

time taken to stop the fever

Timepoint

Hospitalize duration

Method of measurement

from patient documents

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: Patients will receive daily 5µg/kg of G-CSF (Filgrastim brand) in addition to the antibiotic received in accordance to the protocol.

Category

Treatment - Drugs

2

Description

Second intervention group: Patients will receive daily 15µg/kg of G-CSF (Filgrastim brand) in addition to the antibiotic received in accordance to the protocol.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital in Gorgan

Full name of responsible person

Dr Sepide Bagheri

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Taleghani Hospital,janbazan Blv,gorgan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Dr Sepide Bagheri

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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

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Dr Sepide Bagheri

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Dr. Amir Hossein Salimi kordasiabi

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The data can be shared after unidentifiable individuals

When the data will become available and for how long

6 months after completion of the study

To whom data/document is available

Professors and medical students

Under which criteria data/document could be used

It does not matter

From where data/document is obtainable

Send email to salimia92@gmail.com

What processes are involved for a request to access data/document

Use email

Comments

no