

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Efficacy of Allium extract administration in increasing peripheral blood neutrophil count in pediatric cancer patients admitted due to febrile neutropenia

Protocol summary

Summary

We are going to determine if allium extract can speed up bone marrow recovery of cancer patients who are admitted post chemotherapy with febrile neutropenia. 100 patients are equally divided to two groups. Group1 will take filgrastim as well as Allium extract capsule. The other group will take filgrastim and placebo. CBC will be checked daily and the time to bone marrow recovery will be compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015051615666N2**

Registration date: **2015-05-31, 1394/03/10**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-05-31, 1394/03/10

Registrant information

Name

Mohammad Reza Bordbar

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 3239

Email address

bordbarm@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2015-06-01, 1394/03/11

Expected recruitment end date

2016-06-01, 1395/03/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Allium extract administration in increasing peripheral blood neutrophil count in pediatric cancer patients admitted due to febrile neutropenia

Public title

Efficacy of leek vegetable in augmenting the immune system of children with cancer admitted due to fever and infection

Purpose

Treatment

Inclusion/Exclusion criteria

All children in the age range of 4-18 years who suffer from any kind of cancer and admitted post chemotherapy with febrile neutropenia are included. Those with known history of severe hypersensitivity reaction to the leek vegetable or other family members of garlic are excluded.

Age

From **4 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 100

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz university of Medical Sciences

Street address

Zand street- main building of Shiraz University of Medical Sciences

City

Shiraz

Postal code

Approval date

2015-03-06, 1393/12/15

Ethics committee reference number

CT-P-9371-7331

Health conditions studied

1

Description of health condition studied

Post chemotherapy neutropenia in cancer patients

ICD-10 code

D70

ICD-10 code description

Agranulocytosis

Primary outcomes

1

Description

Absolute neutrophil count

Timepoint

daily

Method of measurement

CBC, differential

Secondary outcomes

1

Description

hospital stay

Timepoint

at the time of discharge from hospital

Method of measurement

calculation

Intervention groups

1

Description

Group 1: will take subcutaneous/iv injection of filgrastim 5 microgram/kg daily as well as Allium extract capsule twice daily containing equal to 1200 miligram allium powder. The capsules will be continued for 7 days unless absolute neutrophil count rises to more than 500 which will be withheld sooner.

Category

Treatment - Drugs

2

Description

Group 2 (control):50 patients are included in this group. They will be treated with filgrastim 5microgram/kg sc/IV injection daily the same as group1. However, instead of Allium capsule they will be given placebo capsules twice daily for 7 days unless ANC comes to above 500 which will be discontinued earlier.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Oncology Hospital

Full name of responsible person

Street address

14th station- Farhangshahr street- Amir Hospital

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor of research of Shiraz University of Medical Sciences

Full name of responsible person

Basir Hashemi

Street address

Zand street- main building of Shiraz University of
Medical Sciences

City

Shiraz

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Vice-chancellor of research of Shiraz 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

medical school

Full name of responsible person

mohammadreza bordbar

Position

pediatric hematologist

Other areas of specialty/work

Street address

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**Person responsible for scientific
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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