

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Effect of Nigella sativa seed administration on decreasing of White Blood Cells during chemotherapy among children with ALL

Protocol summary

Study aim

Determination the effect of Nigella sativa on Prevention of Neutropenia During Chemotherapy in Children with ALL

Design

In this study, 132 patients with leukemia with inclusion criteria are divided into three intervention groups. Intervention group 1: group under 5 years receive one capsule containing Nigella sativa , Intervention group 2 : The group between 5-10 years old two capsules containing Nigella sativa and Intervention group 3: group between 10 - 15 years old three capsules containing Nigella sativa .all groups in addition to routine drug receive capsules daily for one months from Barij Essence. After three days the therapeutic effects of the capsule will be assessed and Blood Cells Count checked every week.

Settings and conduct

Clinical trial study Phase 3; Oncology Clinic in shahrekord; Double blind that the researcher and the patient have no information about the contents of the capsules; Allocated to three intervention groups

Participants/Inclusion and exclusion criteria

Children aged 3 to 15 years With cancer undergoing chemotherapy; no other concomitant diseases

Intervention groups

Intervention group 1: Under 5 years old, in addition to routine medications, receive one capsule containing Nigella sativa daily for one month from Barij Essential Capsules during treatment. Intervention group 2: The group is five to ten years old who receive two capsules containing Nigella sativa daily for one month in addition to routine medications from Barij Essential during treatment. Intervention group 3: The group is ten to fifteen years old in addition to routine medications three capsules containing Nigella sativa daily for one month from Barij Essential Capsules during treatment.

Main outcome variables

Complete Blood Count(neutrophils)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191009045035N1**

Registration date: **2019-12-27, 1398/10/06**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-27, 1398/10/06**

Update count: **0**

Registration date

2019-12-27, 1398/10/06

Registrant information

Name

kiavash fekri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3222 0016

Email address

fekri@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Nigella sativa seed administration on decreasing of White Blood Cells during chemotherapy among children with ALL

Public title

Effect of Nigella sativa seed administration on prevention of neutropenia during chemotherapy among children with blood cancer

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Children aged 3 to 15 years With cancer undergoing chemotherapy No other concomitant diseases

Exclusion criteria:

Congenital or acquired immunodeficiency Drug Sensitivity

Age

From **3 years** old to **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

The nigella sativa powder produced in capsules with the same shape and color, and will be coded by the pharmacist, and the codes will be provided only to the supervisor, so that the researcher and the research units will be coded Will be aware.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences

Street address

Vice Chancellor of Research and Technology,
Shahrekord University of Medical Sciences, Kashani
Blvd, Shahrekord, Iran

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Approval date

2019-03-03, 1397/12/12

Ethics committee reference number

IR.SKUMS.REC.1397.258

Health conditions studied

1

Description of health condition studied

Acute lymphoblastic leukemia

ICD-10 code

C91.0

ICD-10 code description

Acute lymphoblastic leukemia [ALL]

Primary outcomes

1

Description

Complete Blood Count

Timepoint

every week

Method of measurement

sampling

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Under 5 years old in addition to routine medications, receive one capsule containing Nigella sativa daily for one month from Barij Essence Capsules containing Nigella sativa during treatment.

Category

Prevention

2

Description

Intervention group 2: The group is five to ten years old who receive two capsules containing Nigella sativa daily for one month in addition to routine medications from Barij Essential during treatment.

Category

Prevention

3

Description

Intervention group 3: The group is ten to fifteen years old in addition to routine medications three capsules containing Nigella sativa daily for one month from Barij Essence Capsules during treatment.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kashani Hospital

Full name of responsible person

Kiavash Fekri

Street address

Kashani Hospital of Shahrekord University of Medical Sciences, Parastar street, Shahrekord, Iran

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Phone

+98 38 3222 0016

Email

fekri@skums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr.Kamal Solati

Street address

Vice Chancellor of Research and Technology,
Shahrekord University of Medical Sciences,Kashani
Blvd, Shahrekord,Iran

City

shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Phone

+98 38 3334 2414

Email

kamal@skums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Research Deputy of Shahrekord 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**

Shahre-kord University of Medical Sciences

Full name of responsible person

Kiavash Fekri

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Kashani Hospital of Shahrekord University of Medical Sciences, Parastar Avenue, Shahrekord, Iran

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shahrekord

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Phone

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Email

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

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Position

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Postal code

8815713471

Phone

0098383220016

Email

fekri@skums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

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Position

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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

Total data in article format

When the data will become available and for how long

one years

To whom data/document is available

researchers

Under which criteria data/document could be used

publication

From where data/document is obtainable

journals

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

En publication of article

Comments