

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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		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
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 yearsWith 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 capsuls 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		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
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		

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
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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

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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

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

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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