

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of soy nut consumption on inflammatory markers, nutritional status, blood and bone marrow cells count and chemotherapy complications in children with acute lymphoblastic leukemia (ALL): A randomized clinical trial

Protocol summary

Summary

This study will be a randomized, single-blind, placebo-controlled, single-center trial which aims to examine the effect of soybean compared to cowpea on nutritional status, blood and bone marrow cells count, inflammatory markers and chemotherapy complications in children with acute lymphoblastic leukemia (ALL). In the present study, after selection of the children based on inclusion criteria and obtaining informed consent from their parents, they will be randomly (based on age groups) assigned into intervention and control groups and will receive, thirty grams of powdered unsalted roasted soybeans or thirty grams of powdered unsalted roasted cowpea flour for three months, respectively. The flours will be provided in sachets which will be mixed with the children's' daily foods (usually soup). Participants will be blinded to the intervention supplements up to the end of the study period. Dietary and supplements intake, physical activity, chemotherapy drugs' dose, anthropocentric indices, side effects of chemotherapy, blood and bone marrow samples will be assessed at the beginning, month one, two and three of the study. Serum inflammatory markers including highly sensitive C-reactive protein (hs-CRP) and tumor necrosis factor alpha (TNF-alpha) will also be assessed for each participant at the start and the end of intervention period. The adherence to the study protocol will be assessed by telephone monitoring, and the participants will be asked to bring back the sachets all the sachets (empty and full) in each monthly visit.

General information

Acronym

The effect of soy nut on acute lymphoblastic leukemia

IRCT registration information

IRCT registration number: **IRCT2016040212571N4**

Registration date: **2017-04-15, 1396/01/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-15, 1396/01/26

Registrant information

Name

Amin Salehi-Abargouei

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 9100

Email address

abargouei@hlth.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2017-06-20, 1396/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of soy nut consumption on inflammatory markers, nutritional status, blood and bone marrow cells count and chemotherapy complications in children with acute lymphoblastic leukemia (ALL): A randomized clinical trial

Public title

The effect of soy nut consumption on inflammatory markers, nutritional status, blood and bone marrow cells count and chemotherapy complications in children with acute lymphoblastic leukemia (ALL)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Participants aged between 3-15 years old who have Acute lymphoblastic leukemia (ALL) confirmed by an oncologist; being in the consolidation phase of treatment (maintenance phase) with regular chemotherapy; Both patient and his/her parent intend to participate in the study; Not being on a specific diet; Subjects who do not have any allergies to soy or cowpea will not be included. Exclusion criteria: Subjects with relapse of the disease complication; lack of consumption of more than 50% of intervention supplements by participants; Occurrence of allergy upon supplements consumption; Subjects or parents who intend to leave the study with any reason.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Shahid Sadoughi University of Medical Sciences

Street address

Chancellery for research, Central Building of Shahid Sadoughi University of Medical Sciences, Bahonar Square, Yazd, Iran

City

Yazd

Postal code

8915173160

Approval date

2016-02-16, 1394/11/27

Ethics committee reference number

IR.SSU.SPH.REC.1394.103

Health conditions studied

1

Description of health condition studied

Acute lymphoblastic leukaemia [ALL]

ICD-10 code

C91.0

ICD-10 code description

Acute lymphoblastic leukaemia [ALL]

Primary outcomes

1

Description

Red blood cells count

Timepoint

At baseline and every month up to three months

Method of measurement

Complete blood count

2

Description

White blood cells counts

Timepoint

At baseline and every month up to three months

Method of measurement

Complete blood count

3

Description

Blood Platelets count

Timepoint

At baseline and every month up to three months

Method of measurement

Complete blood count

4

Description

Blood Lymphocytes count

Timepoint

At baseline and every month up to three months

Method of measurement

Complete blood count

5

Description

Blood Neutrophil count

Timepoint

At baseline and every month up to three months

Method of measurement

Complete blood count

6

Description

Blood Monocytes count

Timepoint

At baseline and every month up to three months

Method of measurement

by complete blood count

7

Description

Blood Eosinophils count

Timepoint

At baseline and every month up to three months

Method of measurement

Complete blood count

8

Description

Blood hemoglobin levels

Timepoint

At baseline and every month up to three months

Method of measurement

Complete blood count (CBC)

9

Description

Bone marrow blast percentage

Timepoint

At baseline and every month up to three months

Method of measurement

based on bone marrow samples

10

Description

Nausea

Timepoint

At baseline and every month up to three months

Method of measurement

The Edmoton Symptom Assessment System (ESAS)

11

Description

Vomiting

Timepoint

At baseline and every month up to three months

Method of measurement

The Edmoton Symptom Assessment System (ESAS)

12

Description

Pain

Timepoint

At baseline and every month up to three months

Method of measurement

The Edmoton Symptom Assessment System (ESAS)

13

Description

Fatigue

Timepoint

At baseline and every month up to three months

Method of measurement

The Edmoton Symptom Assessment System (ESAS)

14

Description

Depression

Timepoint

At baseline and every month up to three months

Method of measurement

The Edmoton Symptom Assessment System (ESAS)

15

Description

Anxiety

Timepoint

At baseline and every month up to three months

Method of measurement

The Edmoton Symptom Assessment System (ESAS)

16

Description

Drowsiness

Timepoint

At baseline and every month up to three months

Method of measurement

The Edmoton Symptom Assessment System (ESAS)

17

Description

Shortness of breath

Timepoint

At baseline and every month up to three months

Method of measurement

The Edmoton Symptom Assessment System (ESAS)

18

Description

Serum Albumin

Timepoint

At baseline and every month up to three months

Method of measurement

Agarose gel electrophoresis

19

Description

hs -CRP

Timepoint

at the beginning and end of intervention

Method of measurement

by appropriate ELISA kit

20

Description

TNF- α

Timepoint

at the beginning and end of intervention

Method of measurement

by appropriate ELISA kit

Secondary outcomes

1

Description

Waist circumferences

Timepoint

at baseline and every month up to three months

Method of measurement

Based on the standard protocol using tape measure

2

Description

Physical activity

Timepoint

at baseline and every month up to three months

Method of measurement

Based on the standard protocol and physical activity record

3

Description

Weight

Timepoint

at baseline and every month up to three months

Method of measurement

by digital scale

4

Description

Energy intake

Timepoint

at baseline and every month up to three months

Method of measurement

Using a three day dietary record

5

Description

Body mass index(BMI)

Timepoint

at baseline and every month up to three months

Method of measurement

Weight (in kilogram) divided by height (in meter) squared

Intervention groups

1

Description

Intervention group: 30 g/day unsalted roasted soybean powder

Category

Treatment - Other

2

Description

control group: 30 g/day unsalted roasted cowpea powder

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyed al shohada hospital

Full name of responsible person

Narges ramezani

Street address

Seyed al shohada hospital, Khayyam highway, Nahr Farshadi alley, Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellery for Research, shahid sadughi University of Medical Sciences

Full name of responsible person

Dr. Amirhushang Mehrparvar

Street address

Chancellery for research, Central Building of Shahid Sadoughi University of Medical Sciences, Bahonar Square, Yazd, Iran

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellery for Research, shahid sadughi 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***City**

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Full name of responsible person

Narges Ramezani

Position

MSc student of Health Sciences in Nutrition

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Full name of responsible person

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Position

PhD in Nutrition Sciences

Other areas of specialty/work**Street address**

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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*