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 committe 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 approprait ELISA kit

20

Description
TNF-α
Timepoint
at the beginning and end of intervention
Method of measurement
by approprait ELISA kit

Secondary outcomes

1

Description
Waist circunfrences
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 Chancellary 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 Chancellary 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

Person responsible for general inquiries

Contact
Name of organization / entity
Nutrition and Food security Research Center, Faculty of Health, Shahid Sadoughi University of Medica
Full name of responsible person
Narges Ramezani
Position
MSc student of Health Sciences in Nutrition
Other areas of specialty/work
Street address
Department of Nutrition, Faculty of Public Health, Shahid Sadughi University of Medical Sciences, Alem Square, Yazd, Iran
City
Yazd
Postal code
8915173160
Phone
+98 35 3820 9100
Fax
+98 35 3820 9119
Email
n.ramezani171@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
School of Public Health, Shahid Sadoughi University of Medical Sciences, Shohaday-e-Gomnam Blvd., Al
Full name of responsible person
Amin Salehi-Abargouei
Position
PhD in Nutrition Sciences
Other areas of specialty/work
Street address
School of Public Health, Shahid Sadoughi University of Medical Sciences, Shohaday-e-Gomnam Blvd., Alem Sq., Yazd, Iran
City
Yazd
Postal code
8915173160
Phone
+98 35 3149 2229
Fax
+98 35 3820 9119
Email
abargouei@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Nutrition and Food Security Research Center, Shahid Sadughi University of medical Sciences, Yazd, Ir
Full name of responsible person
Narges Ramezani
Position
MSc student of Health Sciences in Nutrition
Other areas of specialty/work
Street address
Department of Nutrition, Faculty of Public Health, Shahid Sadughi University of Medical Sciences, Alem Square, Yazd, Iran.
City
Yazd
Postal code
8916978477
Phone
+98 35 3820 9100
Fax
Email
n.ramezani171@yahoo.com
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