Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of oral L-Carnitine on liver enzymes in children diagnosed with ALL in the maintenance phase of therapy: A randomized clinical trial

Protocol summary

Study aim
Investigating the effect of adding oral L-carnitine to the treatment regimen of children with acute lymphoblastic leukemia in the maintenance phase on the level of liver enzymes.

Design
A double-blind randomized clinical trial study using block randomization and stratified by age on 98 patients. Randomization will be done using the software of www.sealedenvelope.com website.

Settings and conduct
The study will be conducted in the hematology and oncology ward of Ali Asghar Hospital in Tehran. The patients in the intervention and placebo groups will undergo the intervention for 2 months, and both groups will be examined every two weeks in terms of the mentioned liver enzymes until the end of the third month from the start of the intervention. Patients, clinical care providers and outcome assessors will be blinded in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Children between 5 and 18 years old with acute lymphoblastic leukemia (ALL) undergoing chemotherapy in the maintenance phase, increased liver function test between grades 1-3, whose parents are satisfied with their child's participation in the study. Exclusion criteria: suffering from opportunistic viral and bacterial infections, suffering liver and kidney dysfunction, and other underlying diseases.

Intervention groups
L-carnitine receiving group, placebo receiving group

Main outcome variables
Serum level of liver enzymes including Alanine transaminase (ALT), Aspartate transferase (AST), Alkaline phosphatase, Bilirubin, and blood platelet count.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201107049296N2**
Registration date: **2023-08-19, 1402/05/28**
Registration timing: **prospective**

Last update: **2023-08-19, 1402/05/28**
Update count: **0**

Registration date
2023-08-19, 1402/05/28

Registrant information

Name
Aziz Eghbali

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2268 8027

Email address
eghbali.a@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-06, 1402/06/15

Expected recruitment end date
2024-04-18, 1403/01/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of oral L-Carnitine on liver enzymes in children diagnosed with ALL in the maintenance phase of therapy: A randomized clinical trial

Public title
Evaluation of the effect of oral L-Carnitine on liver enzymes in children diagnosed with ALL

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Children with acute lymphoblastic leukemia (ALL) Age between 5 and 18 years In maintenance phase of chemotherapy (under treatment with methotrexate and 6-mercaptopurine) The serum level of liver enzymes between two and a half to ten times normal Total bilirubin between 1.5 and 3 mg/dL Gamma glutamyl transferase (GGT) serum level greater than or equal to 60 Parental informed consent to participate in the trial

Exclusion criteria:
Having viral hepatitis, including A, B and C Active infection with any of the Epstein-Barr viruses, Cytomegalovirus, herpes simplex Active bacterial infection Any type of underlying liver dysfunction Renal dysfunction is defined by a creatinine number higher than 2 times the upper normal level Taking aspirin Contracting AIDS Current Hypothyroidism History of epilepsy Sickle cell anemia Suffering from malabsorption disorders

Age
From **5 years** old to **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **98**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the stratified block randomization method will be used using blocks with a size of 4 and stratified according to age. We will use the site https://www.sealedenvelope.com to provide random sequences. For the sequence concealment, it will be given to an independent individual and will be revealed case by case to the project researcher in coded form with A and B labels.

Blinding (investigator's opinion)
Double blinded

Blinding description
Blinding will be done using a placebo syrup identical in form to the original drug. Allocation between the groups is done based on the coded labels A and B on the glass of syrups, and only the independent person responsible for coding is aware of the type of labels.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Iran university of medical science., Next to Milad Tower., Hemmat Highway., Tehran

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2023-01-28, 1401/11/08

Ethics committee reference number
IR.IUMS.FMD.REC.1401.570

Health conditions studied

1

Description of health condition studied
Acute lymphoblastic leukaemia

ICD-10 code
C91.0

ICD-10 code description
Acute lymphoblastic leukaemia

Primary outcomes

1

Description
Serum level of alanine transaminase (ALT)

Timepoint
4, 6, 8, 10 and 12 weeks after the intervention

Method of measurement
Serum spectrophotometry

Secondary outcomes

1

Description

Aspartate transferase (AST) serum level

Timepoint

4, 6, 8, 10 and 12 weeks after the intervention

Method of measurement

Serum Spectrophotometry

2

Description

Blood serum bilirubin level

Timepoint

4, 6, 8, 10 and 12 weeks after the intervention

Method of measurement

Serum spectrophotometry

3

Description

Serum alkaline phosphatase level

Timepoint

4, 6, 8, 10 and 12 weeks after the intervention

Method of measurement

Serum spectrophotometry

4

Description

Blood platelet count

Timepoint

4, 6, 8, 10 and 12 weeks after the intervention

Method of measurement

Cell counter

Intervention groups

1

Description

Intervention group: L-carnitine syrup (Alborz pharmaceutical company, Iran) with a dose of 50 mg/Kg will be given in three times a day every 8 hours for a period of two months. The chemotherapy protocol will be weekly methotrexate at a dose of 20 mg/m2 (body surface) and 6 mercaptopurine daily at a dose of mg/m2 (body surface).

Category

Treatment - Drugs

2

Description

Control group: A placebo of the same shape and color in the same package as the intervention drugs (Alborz pharmaceutical company, Iran) will be used in three divided doses every 8 hours for a period of two months. The chemotherapy protocol will be weekly methotrexate at a dose of 20 mg/m2 (body surface) and 6 mercaptopurine daily at a dose of mg/m2 (body surface).

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Ali Asghar Children's Hospital

Full name of responsible person

Aziz Eghbali

Street address

Ali Asghar Children's Hospital, Zafar St, Modares Hwy

City

Tehran

Province

Tehran

Postal code

1919816766

Phone

+98 21 2304 6413

Email

eghbali.a@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Reza Falak

Street address

Iran University of Medical Sciences, next to the Milad Tower, Hemat Hwy

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2504

Email

rezafalak@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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
Iran University of Medical Sciences

Full name of responsible person
Aziz Eghbali

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

Street address
Aliasghar children’s hospital, Dastgerdi st., Zafar st., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1919816766

Phone
+98 21 2268 8027

Fax

Email
eghbali.a@iums.ac.ir

Person responsible for scientific inquiries

Contact

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Iran University of Medical Sciences

Full name of responsible person
Aziz Eghbali

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Fax

Email
eghbali.a@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Aziz Eghbali

Position
Associate professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Ownership of the data rests with the study sponsor.

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available