Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Comparison the effectiveness and non effectiveness of L-carnitine in improvement of liver enzymes in patients treated with methotrexate and 6-mercaptopurine

Protocol summary

Summary

This study will be done with aim to investigate the effectiveness of L-Carnitine in the improvement of liver enzymes in patients treated with methotrexate and 6-mercaptopurine. This study is a single blind clinical trial. The study population consisted of children with acute lymphoblastic leukemia treated with methotrexate and 6-mercaptopurine that are referred to the Mohammad Kermanshahi hospital of Kermanshah City. 36 persons will selected in available method and randomly will be divided into two groups of(16 persons) tests and controls. Folic acid supplements are given to patients in both groups. In the intervention group 50 mg of L-Carnitine tablets or syrup per kg body weight up to2 grams is prescribed daily for 3 months under the supervision of pediatric specialists. The control group will receive placebo daily 50 mg per kg of body weight up to 2 grams for 3 months. Then in both groups of patients liver enzymes will be examined by blood tests in baseline of study and once every two weeks for 3 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201604297677N5**
Registration date: **2016-05-10, 1395/02/21**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-05-10, 1395/02/21

Registrant information

Name

Mohamadreza Golpayegani

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2016-05-14, 1395/02/25

Expected recruitment end date

2016-08-15, 1395/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effectiveness and non effectiveness of L-carnitine in improvement of liver enzymes in patients treated with methotrexate and 6-mercaptopurine

Public title

Effectiveness of L-Carnitine in improvement of liver enzyme in patients treated with Methotrexate and 6-Mercaptopurine. Treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age less than 18 years; Patient informed consent . Exclusion criteria: Patients with hypothyroidism –seizures; L-carnitine intolerance.

Age
From **1 year** old to **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Randomly by tossing coin

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
City
Kermanshah
Postal code
Approval date
2016-04-27, 1395/02/08
Ethics committee reference number
kums.rec.1395.58

Health conditions studied

1

Description of health condition studied
Acute lymphoblastic leukemia
ICD-10 code
C91.0
ICD-10 code description
Acute lymphoblastic leukaemia [ALL]

Primary outcomes

1

Description
Aspartat Aminotransferase (AST)
Timepoint
Once every two weeks for 3 months
Method of measurement
Based on blood test

2

Description
Alanin Aminotransferase (ALT)
Timepoint
Once every two weeks for 3 months
Method of measurement
By blood test

Secondary outcomes

empty

Intervention groups

1

Description
Folic acid supplements are given to patients in both groups. In the intervention group 50 mg of L-Carnitine tablets or syrup per kg body weight up to2 grams is prescribed daily for 3 months under the supervision of pediatric specialists.
Category
Treatment - Drugs

2

Description
The control group will received placebo daily 50 mg per kg of body weight up to 2 grams for 3 months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr Mohammad Kermanshahi Hospital
Full name of responsible person
Dr. Elaham Pourazar
Street address
Helala Ahmar Crossroads
City
Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Kermanshah University of Medical Sciences
Full name of responsible person
Koroush Hamzehee
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
City
Kermanshah
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Kermanshah 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
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Full name of responsible person
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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