

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 to 2 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)

Phone

+98 83 1427 6331

Email address

golpayegani@kums.ac.ir

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 to 2 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**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Elaham Pourazar

Position

Resident of Pediatric

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

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Postal code**Phone**

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Fax**Email**

pourazar.emd81@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Golpayegani

Position

Oncologists and Hematologists

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Elaham Pourazar

Position

Resident of Pediatric

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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