Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect of L-carnitine on the prevention of PEG-Asparaginase-induced hepatitis in patients with acute lymphoblastic leukemia

Protocol summary

Study aim

Evaluation of the effect of L-carnitine on the prevention of PEG-Asparaginase-induced hepatitis in patients with acute lymphoblastic leukemia

Design

Clinical trial with a control group/double-blind and randomized.

Settings and conduct

Patients with acute lymphoblastic leukemia admitted to the pediatric oncology department and treated with PEG-Asparaginase. In the intervention group, L-carnitine is administered to patients from the second day of hospitalization until 14 days after receiving PEG-Asparaginase. The studied patients and the patient's caregivers are not aware of the type of drug used in each patient-episode.

Participants/Inclusion and exclusion criteria

Inclusion Criteria : 1-Patients from 1 month to 18 years old with acute lymphoblastic leukemia of B cells hospitalized in the oncology department of BouAliSina Hospital treated with COG protocol. 2-The normal level of liver enzymes at the beginning of the study. Exclusion Criteria: 1-lack of satisfaction 2-underlying liver disorder 3-underlying metabolic disorder involving the liver 4-Having viral hepatitis 5-taking hepatotoxic drugs 6-An increase in bilirubin or an increase in liver transaminases above normal values before starting the study 7-Contraindication or allergy to L-carnitine

Intervention groups

A double-blind study on children from one month to 18 years old with B-cell acute lymphoblastic leukemia who are treated with PEG-Asparaginase in the induction phase of the treatment protocol.In the intervention group, L-carnitine at a dose of 50 mg/kg/day every 12 hours is administered orally to patients from the second day of hospitalization until 14 days after receiving PEG-Asparaginase. In the control group, from the second day of hospitalization to the 14th day after receiving asparaginase, placebo is given every 12 hours.

Main outcome variables

Total Bill, Direct Bill, ALT, AST, ALK-P, PT, PTT, FBS, BUN, Cr, Uric Acid

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190202042583N4**
Registration date: **2023-11-06, 1402/08/15**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-06, 1402/08/15**
Update count: **0**

Registration date

2023-11-06, 1402/08/15

Registrant information

Name
Mohammad Naderisorki
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 11 3334 7837
Email address
dr.naderisorki@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of L-carnitine on the prevention of PEG-Asparaginase-induced hepatitis in patients with acute lymphoblastic leukemia

Public title
Evaluation of the effect of L-carnitine on the prevention of drug induced hepatitis
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
getting acute lymphoblastic leukemia normal enzyme levels at the beginning of the study
Exclusion criteria:
underlying liver disease underlying metabolic disease involving the liver (galactosemia-tyrosinemia-...) Viral hepatitis Use of hepatotoxic drugs Elevation of bilirubin or liver transaminases above normal values before the start of the study Contraindication or allergy to L-carnitine
Age
From **1 month** old to **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **38**
Randomization (investigator's opinion)
Randomized
Randomization description
We divide each client into two groups using a random table. This table is a set of numbers. Consider the numbers 1 to 19 for intervention A and the numbers 20 to 38 for control B (for both size groups larger and smaller than 4 cm). Then we touch one of the numbers and move into one of the predetermined directions and record the numbers and assign them to one of the groups. In this way, patients are divided completely randomly.
Blinding (investigator's opinion)
Double blinded
Blinding description
On the pharmaceutical form and the main drug, which is prepared by the project's pharmaceutical team, stickers containing Latin numbers and letters are attached, and these numbers and letters are recorded secretly. Medicines and placebos are delivered to the department. When it is necessary to prescribe medicine, with the coordination of the project executive resident (who is not aware of the type of medicine or placebo), the medicine is given to the patient randomly. The tag number is recorded in the data collection form. In the studies, the type of preparation of the drug or placebo is determined based on the equality of registration of labels and forms. The resident who implements the plan and the patient and the patient's parents will not have any information about the contents of the plan.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences
Street address
Central Headquarters of Mazandaran University of Medical Sciences, at the beginning of Valiasr Highway
City
sari
Province
Mazandaran
Postal code
3397148157
Approval date
2023-01-04, 1401/10/14
Ethics committee reference number
ir.mazums.rec.1401.444

Health conditions studied

1

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

Primary outcomes

1

Description
Drug induced Hepatitis
Timepoint
before receiving the drug to 14 days after receiving PEG-Asparaginase
Method of measurement
by the clinical supervisor accompanying the plan and

according to the criteria of the World Health Organization

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Before entering the induction phase, preliminary tests are taken from each patient according to the protocol, which are recorded daily until the fourteenth day after receiving asparaginase. L-carnitine is administered orally at a dose of 50 mg/kg per day every 12 hours. The patient's changes are recorded daily by the clinical caregiver, and if hepatitis occurs and the level of liver enzymes increases to double the normal state, the study is stopped and started ursodeoxycolic for patient treatment.

Category

Prevention

2

Description

Control group: Before entering the induction phase, initial tests are taken from each patient according to the protocol, which are recorded daily until the 14th day after receiving Asparaginase. From the second day of hospitalization to the 14th day after receiving asparaginase, placebo is given every 12 hours. The placebo will be prepared by the pharmacist of the plan, which will be similar in shape, size, color and taste to the drug.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu Ali Sina Hospital

Full name of responsible person

Mohammad Naderisorki

Street address

Bu Ali Sina Hospital, Pasdaran Bulv.

City

Sari

Province

Mazandaran

Postal code

3397148157

Phone

+98 11 3334 3018

Email

dr.naderisorki@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Mohammad Naderisorki

Street address

Bu Ali Hospital, Pasdaran Bulv.

City

sari

Province

Mazandaran

Postal code

3397148157

Phone

+98 11 3334 4506

Email

dr.naderisorki@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Dr.Mohammad Naderisorki

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Mohammad NaderiSorki

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

Street address

Bu Ali Sina Hospital, Pasdaran Bulv.

City

sari

Province

Mazandaran

Postal code

4815838477

Phone

+98 11 3334 7837

Email

dr.naderisorki@mazums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Mohammad Nadeisorki

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

Street address

Bu Ali Sina Hospital, Pasdaran Bulv.

City

sari

Province

Mazandaran

Postal code

4815838477

Phone

+98 11 3334 7837

Email

dr.naderisorki@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Mohammad Naderisorki

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

Street address

Bu Ali Sina Hospital, Pasdaran Bulv.

City

sari

Province

Mazandaran

Postal code

4815838477

Phone

+98 11 3334 7837

Email

dr.naderisorki@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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