Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

Efficacy of L-carnitine in decrease of liver enzymes and liver fat content in patients with non-alcoholic fatty liver disease

Protocol summary

Study aim
Assessment of the efficacy of L-carnitine in treating patients with non-alcoholic fatty liver disease, including improvement in laboratory parameters and liver fat content

Design
The clinical trial, consisting of a control group, parallel groups, double-blind design, and randomization, is conducted in Phase 3 on 102 patients. Excel's rand function was used for randomization

Settings and conduct
L-carnitine, which plays a crucial role in lipid metabolism and beta-oxidation, has drawn researchers' attention for nonalcoholic fatty liver disease. In this study, a multicenter, double-blind study firstly, the metabolic profile of participants would be determined and record. Then, participants in the group LC will receive LC at a dose of 1000 mg twice a day for 3 months, and other group receive placebo. Then reevaluate for liver enzymes and hepatic fat status using ultrasound. Finally, these parameters would be assessed and compare between the two groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: - Age over 15 years - AST, ALT levels above the normal range - Sonographic findings consistent with fatty liver - No history of viral hepatitis or conditions such as hemochromatosis, Wilson’s disease, autoimmune hepatitis, alpha-1 antitrypsin deficiency, or chronic liver disease Exclusion criteria: - Development of evidence of chronic liver disease - Significant alcohol consumption - History of allergy to medication - Pregnant or breastfeeding women

Intervention groups
Patients diagnosed with non-alcoholic fatty liver disease by adult gastroenterologists and hepatologists are randomly assigned to two groups: one receiving L-carnitine supplements, at a dose of 1000 milligrams twice daily for three months, and the other receiving a placebo with a similar administration schedule.

Main outcome variables
Reduction in serum liver enzymes; decrease in hepatic fat levels on ultrasound.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240129060837N1**
Registration date: **2024-03-15, 1402/12/25**
Registration timing: **prospective**

Last update: **2024-03-15, 1402/12/25**
Update count: **0**
Registration date
2024-03-15, 1402/12/25

Registrant information
Name
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Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-03-24, 1403/01/05
Expected recruitment end date
2024-06-20, 1403/03/31
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of L-carnitine in decrease of liver enzymes and liver fat content in patients with non-alcoholic fatty liver disease

Public title

The effect of L-carnitine in non-alcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

AST, ALT levels above the normal range Sonographic findings consistent with fatty liver No history of viral hepatitis or conditions such as hemochromatosis, Wilson’s disease, autoimmune hepatitis, alpha-1 antitrypsin deficiency or chronic liver disease

Exclusion criteria:

Significant alcohol consumption (more than 10 grams per day for women and more than 20 grams per day for men) Pregnant or breastfeeding women

Age

From **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization process will be such that, based on a predetermined list including the patient's row number and the type of intervention (drug or placebo) randomly assigned (Excel's rand function was used for randomization), eligible individuals will be sequentially enrolled into either the drug or placebo group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, after obtaining informed consent from the patient regarding participation, the type of intervention (drug or placebo) is not disclosed. The visiting physician, guided by a pre-randomized list, determines whether the patient should receive the drug or placebo. However, other colleagues receiving intervention results for evaluation and analysis will remain unaware of which group the patient belonged to.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Imam Khomeini educational and therapeutic center, Azadegan St, Ahvaz, Khuzestan province

City

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Province

Khouzestan

Postal code

6193673166

Approval date

2024-03-11, 1402/12/21

Ethics committee reference number

IR.AJUMS.REC.1402.690

Health conditions studied

1

Description of health condition studied

Nonalcoholic fatty liver disease

ICD-10 code

K76

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Decreased level of liver enzymes

Timepoint

Measurement of liver enzymes at the beginning of the study (before the start of the intervention) and 3 months after L-carnitine supplementation

Method of measurement

Check the level of liver enzymes in the serum by the laboratory

2

Description

Reducing the amount of liver fat

Timepoint

Measurement of liver enzymes at the beginning of the study (before the start of the intervention) and 3 months after L-carnitine supplementation

Method of measurement
Tansabdominal ultrasound

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Taking L-carnitine supplement at a dose of one gram every 12 hours for 3 months
Category
Treatment - Drugs

2

Description
Control group: Taking placebo at a dose of one gram every 12 hours for 3 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini educational and therapeutic center
Full name of responsible person
Ahmad Nezhadisalami
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
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Position
assistant professor
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Person responsible for updating data

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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