

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Evaluation of L-carnitine effect in non- alcoholic fatty liver disease (NAFLD) treatment in children

Protocol summary

Study aim

Evaluation of L-carnitine medicinal effect in non alcoholic fatty liver

Design

A concealed, randomized, blinded, sham controlled clinical trial with a parallel group design of 100 patients, enrolled between september 2018 and March 2019, and followed for 3 months

Settings and conduct

Patients with non alcoholic fatty liver that refer to Gastrointestinal unit of Isfahan Imam Hossein hospital are divided to intervention and control group . L-carnitine tablet is given to intervention group and placebo is given to control group.

Participants/Inclusion and exclusion criteria

•Inclusion criteria: 1- Children with non alcoholic fatty liver 2- Age 5-15 years old 3-Liver enzyme elevation excess than 40 unit/lit and diagnosis of fatty liver in sonography. •Exclusion criteria: 1-Viral Hepatitis or auto immune, Diabetes, Hemochromatosis, Cirrhosis, infectious disease, hypothyroidism 2-Consumption of drugs that effect on liver enzyme during last two months 3-Alcohol consumption 4-Discontinuing the study by the patient or his/her family

Intervention groups

Intervention group:5 to 15 years old children with non alcoholic fatty liver who received l-carnitin. Control group:5 to 15 years old children with non alcoholic fatty liver who received placebo.

Main outcome variables

To obtain an appropriate drug to cure fatty liver in children

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170628034786N2**

Registration date: **2019-01-16, 1397/10/26**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-16, 1397/10/26**

Update count: **0**

Registration date

2019-01-16, 1397/10/26

Registrant information

Name

Majid Khademian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3844 0350

Email address

m.khademian@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of L-carnitine effect in non- alcoholic fatty liver disease (NAFLD) treatment in children

Public title

Evaluation of L-carnitine effect in fatty liver treatment in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children with non- alcoholic fatty liver disease Age between 5-15 years old Elevation of liver enzyme more than 40 Unit/Litre Evidence of fatty liver in sonography

Exclusion criteria:

Diagnosis of liver disease other than NAFLD such as :
Viral hepatitis,Autoimmune hepatitis,Diabetes,Hemochromatosis,Cirrhosis,Infectious disease,Hypothyroidism Consumption of drugs that effect on liver enzyme during last two months Alcohol consumption Discontinuing the study by the patient or his/her family

Age

From **5 years** old to **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Using random allocation software , patients randomly will allocate to the intervention and control groups.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this research, patient, researcher, person who gives drug, information collector and data analyzer do not know which patient receive drug and which one receive placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan medical university

Street address

Imam Hossein hospital, Imam Khomeini Ave.

City

Isfahan

Province

Isfahan

Postal code

8195163381

Approval date

2018-12-17, 1397/09/26

Ethics committee reference number

IR.MUI.MED.REC.1397.171

Health conditions studied

1

Description of health condition studied

Non alcoholic fatty liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Measurement of serum liver specific enzyme level (Alanine aminotransferase)

Timepoint

Three months after treatment initiation with placebo and L-carnitine

Method of measurement

Quantitative measurement of liver transaminase and liver sonography

Secondary outcomes

1

Description

Assessment of body mass index

Timepoint

Three months after treatment initiation with placebo and L-carnitine

Method of measurement

Measurement of height and weight and ratio of weight to square of height

Intervention groups

1

Description

Control group: Given placebo twice a day for 3 month

Category

Placebo

2

Description

Intervention group: Given Lcarnitine tablet twice a day for 3month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam hossein hospital gastrointestinal clinic

Full name of responsible person

majid khademian

Street address

Imam khomeini Ave.

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+98 31 3386 8247

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majidkhademian@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Majid khademian

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Grant name

Esfahan University of Medical science

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Majid Khademian

Position

assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

leila khalilian

Position

resident

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

After the implementation of the research the results will be available to the scientific community.

When the data will become available and for how long

One Year after of publication

To whom data/document is available

Professional Researchers in this field

Under which criteria data/document could be used

After communication with the corresponding author of the project, the researchers in this field can access some statistical analysis file information.

From where data/document is obtainable

Principal Investigator Dr. Majid Khademian Isfahan University of Medical Sciences, Faculty of Medicine, Pediatric Department of Gastroenterology, 09133711058 m.khademian@med.mui.ac.ir

What processes are involved for a request to access data/document

After E-Mail to the corresponding author of the project, they will be able to provide the documentation to them.

Comments