Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 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, hypothiroidism 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 ofIsfahan medical university
Street address
Imam Hossein hospital, Imam Khomeini Ave.
City
Isfahan
Province
Isfehan
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
Assaiment 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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Isfahan

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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

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

majid khademian

Position

assistant professor

Latest degree

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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
Pediatrics
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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