Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Assessment of the effectiveness of L-carnitine and curcumin in the treatment of non-alcoholic fatty liver in patients aged 5 to 15 years old

Protocol summary

Study aim
The purpose of this study was to compare the effectiveness of L-cartin and curcumin in the treatment of non-alcoholic fat in patients aged 5 to 15 years referred to Qods Hospital in Qazvin.

Design
Uncontrolled, parallel-group, unblinded, randomized, on 66 patients. The balance block randomization method was used for randomization.

Settings and conduct
A comparison of the effectiveness of L-carnitine and curcumin in the treatment of non-alcoholic fatty liver disease in patients referred to Qods Hospital in Qazvin will be investigated. For a group with 33 patients, two L-carnitine tablets and for a group with 33 patients, curcumin soft gel, once daily, for 8 weeks. After three months the patients are examined again.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients 5 to 15 years old, patients with non-alcoholic fatty liver. Exclusion criteria: Patients with specific diseases, patient allergies to curcumin or L-carnitine.

Intervention groups
For a group of 33 patients, L-carnitine tablets are prescribed and two L-carnitine tablets are taken daily for 8 weeks. For a group with 33 patients, curcumin soft gel is prescribed and one curcumin soft gel is eaten daily for 8 weeks.

Main outcome variables
Fatty liver degree and lipid profile are checked before and after treatment.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210412050944N2**
Registration date: **2022-10-10, 1401/07/18**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-10, 1401/07/18**
Update count: **0**

Registration date
2022-10-10, 1401/07/18

Registrant information
Name
Fatemeh Tohidnia
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 28 3332 8709
Email address
cgd.rc@qums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-23, 1401/07/01

Expected recruitment end date
2022-12-22, 1401/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Assessment of the effectiveness of L-carnitine and curcumin in the treatment of non-alcoholic fatty liver in patients aged 5 to 15 years old

Public title
Assessment of the effectiveness of L-carnitine and curcumin in the treatment of non-alcoholic fatty liver

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are between 5 to 15 years old. Patients who have increased their liver enzymes more than 40 units per liter. Patients who have been diagnosed with fatty liver in ultrasound. Patients who have been diagnosed with non-alcoholic fatty liver disease by pediatric gastroenterology specialist. Patients who parents consent to participate in this plan.
Exclusion criteria:
Patients who suffering from viral hepatitis. Patients who suffering from diabetes. Patients who have taken drugs affecting liver tests in the last 2 months. Patients who suffering from hemochromatosis. Patients who suffering from cirrhosis. Patients who who suffering from addicted to alcohol Patients who suffering from infectious diseases. Patients who suffering from hypothyroidism. Patients who are allergic to curcumin or L-carnitine. Patients who suffering from hypothyroidism. Patients who have not completed the medication for 3 months
Age
From **5 years** old to **15 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **66**
More than 1 sample in each individual
Number of samples in each individual: **33**
Patients group with L-carnitine medicine /(33 patients with non-alcoholic fatty liver disease) and patients group with curcumin medicine /(33 patients with non-alcoholic fatty liver)
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are assigned to two treatment groups A and B using the randomized block design method. The randomization unit is individual. The size of each block is 6 and the total number of blocks is 11. The method of balanced randomization allocation for the participants in the randomized controlled clinical trial study of curcumin (group A) and L-carnitine (group B) effect on reducing non-alcoholic fatty liver grade is performed. Allocation concealment is done by central randomization. In this method, a random sequence is available to the researcher, and sampling is done in one center. Based on the order in which the participants entered the study, the researcher communicates with the relevant center and asks about the random allocation of the participants to a specific group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Qazvin University of Medical Sciences
Street address
Beginning of East Palestine Ave., Shahid Beheshti Blvd., Qazvin Town
City
Qazvin
Province
Qazvin
Postal code
14595-34159
Approval date
2022-03-14, 1400/12/23
Ethics committee reference number
IR.QUMS.REC.1400.408

Health conditions studied

1

Description of health condition studied
Non-alcoholic fatty liver
ICD-10 code
E88.9
ICD-10 code description
Metabolic disorder, unspecified

Primary outcomes

1

Description
Percentage of children with non-alcoholic fatty liver
Timepoint
Before the intervention and 3 months after the administration of L-carnitine and curcumin in the intervention groups
Method of measurement
Ultrasonography and biochemical tests

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: For a group of 33 patients, L-carnitine tablets are prescribed at a dose of 50 milligrams per kilogram of body weight in one day (Karen Pharmaceutical Company, Iran). Two L-carnitine tablets, every 12 hours, for 8 weeks daily are given to the patient. All the tests are done before drug administration and three months after drug administration for the patient. The number of educational sessions is four sessions (before prescribing medicine, at the end of the first month, at the end of the second month, and at the end of the third month) for parents. The session's content includes; training on how to take the drug, side effects, beneficial effects, how to treat and the mechanism of action of L-carnitine in the body, and how to evaluate the child's treatment. The duration of training sessions is one hour and the duration of the course is three months.

Category

Treatment - Drugs

2

Description

Intervention group: For a group of 33 patients, Sina curcumin nanomicelle soft gel is prescribed at a dose of 40 milligrams (Exir Nano Sina Pharmaceutical Company, Iran). One Sina curcumin nanomicelle soaftgel, every 24 hours, for 8 weeks on a daily basis are given to the patient. The number of educational sessions is four sessions (before prescribing medicine, at the end of the first month, at the end of the second month, and at the end of the third month) for parents. The content of the session includes; training on how to take the drug, side effects, beneficial effects, how to treat and the mechanism of action of Sina curcumin nanomicelle soaftgel in the body, and how to evaluate the child's treatment. The duration of training sessions is one hour and the duration of the course is three months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Qods hospital

Full name of responsible person

Somayeh Janani

Street address

Beginning of East Palestine Ave., Shahid Beheshti Blvd., Qazvin Town

City

Qazvin

Province

Qazvin

Postal code

14595-34159

Phone

+98 28 3332 8709

Email

somayeh_janani1361@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Seyed Mehdi Mirhashemi

Street address

Beginning of East Palestine Ave., Shahid Beheshti Blvd., Qazvin Town

City

Qazvin

Province

Qazvin

Postal code

14595-34159

Phone

+98 28 3332 8709

Email

somayeh_janani1361@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Somayeh Janani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Beginning of East Palestine Ave., Shahid Beheshti Blvd., Qazvin Town

City

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Postal code
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Phone
+98 28 3332 8709

Email
somayeh_janani1361@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Somayeh Janani

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Pediatrics

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Phone
+98 28 3332 8709

Email
somayeh_janani1361@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Somayeh Janani

Position
Assistant professor

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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
Yes - There is a plan to make this available

Title and more details about the data/document
All parts of the Excel file of the participant's data will be provided to the researchers after removing the participants' private information. The study protocol and statistical analysis map can be provided to the researchers by mentioning the reference and the present project as a source. In order to maintain ethical rules, the informed consent form will be provided to the relevant institution and researcher who will use the data of this project. The clinical study report is provided to researchers in the form of a flow diagram. The codes used in the analysis and the data classification system used for the implementation of the new study in line with the continuation of the current project will be available to the researchers as a source and model with references. All the items mentioned will be used during ethical and legal procedures.

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
The data will be available to researchers working in academic and non-academic scientific institutions and pharmaceutical companies and can apply to receive them.

Under which criteria data/document could be used
Researchers will send their written request to the project manager, stating reasons and details for access to data and documents. After review by the ethics committee and the research council, if approved, it will be sent.

From where data/document is obtainable
Researchers will send a written request to executor of the project stating the reasons and details for accessing the data and documentation.

What processes are involved for a request to access data/document
The applicant will send his written request to the project manager with reasons and details for access to data and documents. After approval by the project manager, the project manager will send the request to the research assistant. After communicating with the applicant institution or person and providing the necessary explanations to the applicant, the request will be submitted to the university's ethics committee. If approved by the ethics committee, documents and

information files will be provided to the applicant. This process takes 6 months.

Without the approval of the ethics committee, the information will not be provided to the applicants.

Comments