Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Nov 2026

Evaluation of the effectiveness of Curcumin on fatty liver disease in children

Protocol summary

Study aim
Evaluation of the effectiveness of Curcumin on fatty liver disease in children nd placebo before and after the interventions

Design
A clinical trial with a control group, with parallel groups, triple blind, randomized, phase 3 on 60 patients.

Settings and conduct
Patients with non-alcoholic fatty liver referred to clinics affiliated with Isfahan University of Medical Sciences will be divided into control and intervention groups. Nanomiecelle curcumin soft gel will be given to the intervention group and a placebo will be given to the control group. Patients, physicians, researchers, and drug distributors will not know which patient will be given medication or placebo.

Participants/Inclusion and exclusion criteria
To be eligible for the study, the child must be between 5 and 16 years old and have fatty liver disease confirmed by a pediatric gastroenterologist (other causes of elevated liver enzymes and increased hepatic echogenicity on ultrasound should be ruled out). If the child is allergic to curcumin or turmeric, it will be excluded from the study.

Intervention groups
Intervention group: Patients in this group receive a 40 or 80 mg nanomiecell curcumin soft gel daily for 8 weeks. Control group: Placebo is taken once a day, which is completely similar to the original soft gels in terms of color, size and smell.

Main outcome variables
Serum levels of alanine aminotransferase; Serum levels of aspartate aminotransferase; Degree of fatty liver on ultrasound.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170628034786N4**
Registration date: **2021-07-04, 1400/04/13**
Registration timing: **prospective**

Last update: **2021-07-04, 1400/04/13**
Update count: **0**

Registration date
2021-07-04, 1400/04/13

Registrant information

Name
Majid Khademian

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3844 0350

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m.khademian@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-22, 1400/04/31

Expected recruitment end date
2022-04-20, 1401/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of Curcumin on fatty liver disease in children

Public title

Evaluation of the effectiveness of Curcumin on fatty liver disease in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Non-alcoholic fatty liver disease confirmed by a pediatric gastroenterologist Patient parents' consent to participate in this project

Exclusion criteria:

Allergy to curcumin

Age

From **5 years** old to **16 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

During random allocation, patients will be divided into two groups of interventional and placebo by permutation block method with blocks of volume 4. (Possible permutations are: AABB, ABAB, ABBA, BBAA, BABA, BAAB). Using the random permutation block method, the samples will be assigned to two groups. Random sequences are generated using R software and a random allocation software package

Blinding (investigator's opinion)

Triple blinded

Blinding description

The medication and placebo will be prepared by the pharmacist. They are exactly the same in appearance, color, and smell. Then each will be placed in a bag and marked as A or B on the cover. The way of prescription is the same in both groups. The researcher, patient, and statistician who analyzes the data will not be aware of the patient's grouping.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib street

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2021-06-21, 1400/03/31

Ethics committee reference number

IR.MUI.MED.REC.1400.222

Health conditions studied

1

Description of health condition studied

NAFLD

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

serum level of Alanine aminotransferase

Timepoint

8 weeks after the initiation of treatment

Method of measurement

Quantitative measurement of liver transaminase

2

Description

serum level of Aspartate aminotransferase

Timepoint

8 weeks after the initiation of treatment

Method of measurement

Quantitative measurement of liver transaminase

Secondary outcomes

1

Description

Body mass index

Timepoint

Before the intervention, 8 weeks after the initiation of treatment

Method of measurement

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

2

Description
Fasting Blood Sugar
Timepoint
Before the intervention, 8 weeks after the initiation of treatment
Method of measurement
Quantitative measurement of serum Fasting Blood Sugar

3

Description
Lipid profile(Chol,TG,HDL,LDL)
Timepoint
Before the intervention, 8 weeks after the initiation of treatment
Method of measurement
Quantitative measurement of serum lipid profile(Chol, TG, HDL,LDL)

4

Description
Alkaline phosphatase
Timepoint
Before the intervention, 8 weeks after the initiation of treatment
Method of measurement
Quantitative measurement of serum Alkaline phosphatase

Intervention groups

1

Description
Intervention group: Patients will receive a 40 or 80 mg nanomicelle sina curcumin soft gel daily for 8 weeks.
Category
Treatment - Drugs

2

Description
Control group: The placebo will be taken once a day , which is quite similar in color and size to the main medicine
Category
Placebo

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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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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Email
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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
Esfahan University of Medical Sciences
Proportion provided by this source
80
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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Person responsible for updating data

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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 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, 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