

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Aug 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 and 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. Nanomicelle 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 nanomicelle 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)

Phone

+98 51 3844 0350

Email address

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

Isfahan

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

City

Isfahan

Province

Isfahan

Postal code

8195163381

Phone

+98 31 3386 8247

Email

m.khademian@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

Street address

Hezar Jerib

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3386 8247

Email

m.khademian@med.mui.ac.ir

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
Street address
Imam khomeini Ave.
City
Isfahan
Province
Isfahan
Postal code
8195163381
Phone
+98 31 3386 8247
Email
m.khademian@med.mui.ac.ir

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
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Imam Khomeini Ave.
City
Isfahan
Province
Isfahan
Postal code
8195163381
Phone
+98 31 3386 8247
Email
m.khademian@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Narges Zare
Position
resident
Latest degree
Specialist

Other areas of specialty/work

Pediatrics
Street address
Imam khomeini Ave.
City
Isfahan
Province
Isfahan
Postal code
8195163381
Phone
+98 31 3386 9141
Email
n.zare132@gmail.com

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