

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The effect of curcumin-piperine supplementation on glycemic indices, lipid profiles, anthropometric indices and liver function in children with none- alcoholic fatty liver disease

Protocol summary

Study aim

determination of the effect of curcumin-piperine supplementation on glycemic indices, lipid profiles, anthropometric indices and liver function in children with none- alcoholic fatty liver disease

Design

Randomized clinical trial, double-blind, randomized control group of 60 patients. Randomization is done using a valid website and 4-block method.

Settings and conduct

This study will be performed in imam hossein children's Hospital, Isfahan. The researchers, participants will be unaware of assigned treatments.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of NAFLD (grades 1-3) according to liver ultrasonography children with BMI percentile ≥ 85 for age age 10-18 years old Exclusion criteria: presence of hepatitis, Chronic liver disease , Cardiovascular, renal, Pulmonary, Hypothyroidism diseases and cancer not consuming drugs that could affect on ALT level including HMG-COA reductase inhibitors, metformin

Intervention groups

intervention group: capsules containing curcumin-piperine each containing 500 mg of curcumin and 5 mg of piperine once a day. control group one capsule each containing 500 mg of maltodextrin

Main outcome variables

glycemic indices, lipid profiles, anthropometric indices, Liver function

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20171107037302N2**

Registration date: **2021-11-14, 1400/08/23**

Registration timing: **prospective**

Last update: **2021-11-14, 1400/08/23**

Update count: **0**

Registration date

2021-11-14, 1400/08/23

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3434 3834

Email address

s.sarafbank@nutr.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-09-06, 1401/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of curcumin-piperine supplementation on glycemic indices, lipid profiles, anthropometric indices and liver function in children with none- alcoholic fatty liver disease

Public title

curcumin-piperine supplementation in children with none- alcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

diagnosis of NAFLD (grades 1-3) according to liver ultrasonography children with BMI percentile ≥ 85 for age age 10-18 years old

Exclusion criteria:

presence of hepatitis, Chronic liver disease , Cardiovascular, renal, Pulmonary, Hypothyroidism diseases and cancer not consuming drugs that could affect on ALT level including HMG-COA reductase inhibitors, metformin

Age

From **10 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done individually. Entry of each patient into the intervention or control group is done randomly with the help of 4 blocking. This is done using a reputable random number generation website. (Random number generation website: <https://www.sealedenvelope.com/simple-randomiser/v1/lists>)

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, children will not be aware of received intervention. furthermore, before the beginng of intervention, curcumin supplements and their placebo which are completely similar to each other, will be coded to A and B by a third person rather than main researcher to keep blindness of study.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee Vice-Chancellor in Research Affairs - Medical University of Isfahan

Street address

School of Nutrition and Food Sciences, Isfahan University of Medical Sciences, Hezar-jerib Avenue

City

isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-10-20, 1400/07/28

Ethics committee reference number

IR.MUI.RESEARCH.REC.1400.303

Health conditions studied**1****Description of health condition studied**

none- alcoholic fatty liver disease

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes**1****Description**

weight

Timepoint

At the beginning of study - week 10

Method of measurement

Seca scale

2**Description**

height

Timepoint

At the beginning of study - week 10

Method of measurement

Strip meter

3**Description**

waist circumference

Timepoint

At the beginning of study - week 10

Method of measurement

strip meter

4**Description**

hip circumference
Timepoint
At the beginning of study - week 10
Method of measurement
strip meter

5

Description
Body mass index
Timepoint
At the beginning of study - week 10
Method of measurement
formula

6

Description
Fasting blood sugar
Timepoint
At the beginning of study - week 10
Method of measurement
biochemical assessment

7

Description
triglycerides
Timepoint
At the beginning of study - week 10
Method of measurement
biochemical assessment

8

Description
low-density lipoprotein
Timepoint
At the beginning of study - week 10
Method of measurement
biochemical assessment

9

Description
high-density lipoprotein
Timepoint
At the beginning of study - week 10
Method of measurement
biochemical assessment

10

Description
Total cholesterol
Timepoint
At the beginning of study - week 10
Method of measurement
biochemical assessment

11

Description
Alanine aminotransferase

Timepoint
At the beginning of study - week 10
Method of measurement
biochemical assessment

12

Description
Aspartate aminotransferase
Timepoint
At the beginning of study - week 10
Method of measurement
biochemical assessment

Secondary outcomes

1

Description
Fasting insulin
Timepoint
At the beginning of study - week 10
Method of measurement
biochemical assessment

Intervention groups

1

Description
Intervention group: Intervention group will receive a capsule containing curcumin-piperine in the amount of 500 mg of curcumin and 5 mg of piperine once a day for 10 weeks.
Category
Treatment - Drugs

2

Description
Control group: The control group will receive capsules containing placebo. Each capsule contains 500 mg of maltodextrin for 10 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
imam Hossein children's Hospital
Full name of responsible person
Mohaddese Abdi
Street address
Imam Khomeini Street - before Esteghlal Square
City
Isfahan
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Postal code

8195163381
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m.abdi4015@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Behruz Ataei
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ethics@behdasht.gov.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
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
Sahar Saraf-Bank
Position
Assistant Professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available