Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
Isfehan
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 begining 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
Province
Isfehan
Postal code

8195163381

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+98 31 3386 6266

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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

Street address
Hezar-jerib Ave

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8174673461

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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

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Hezar jarib street, Isfahan University of Medical Sciences, Nutrition and Food Sciences School

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Person responsible for scientific inquiries

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Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
nutrition

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Person responsible for updating data

Contact

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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