Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of curcumin-piperine supplementation on inflammatory and oxidative stress factors, sonographic findings and symptom of depression, anxiety and stress in children with nonalcoholic fatty liver disease

Protocol summary

Study aim
The effect of curcumin-piperine supplementation on inflammatory and oxidative stress factors, sonographic findings and symptom of depression, anxiety and stress in children with nonalcoholic 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: Children with non alcoholic fatty liver, 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 Alanine aminotransferase 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
Inflammatory and oxidative stress factors, Sonographic findings

General information

Reason for update

Acronym
ندارد

IRCT registration information
IRCT registration number: **IRCT20121216011763N54**
Registration date: **2022-03-28, 1401/01/08**
Registration timing: **registered_while_recruiting**

Last update: **2022-03-28, 1401/01/08**
Update count: **0**

Registration date
2022-03-28, 1401/01/08

Registrant information
Name
Gholamreza Askari
Name of organization / entity
Isfahan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 31 1792 2110
Email address
askari@mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-12, 1400/12/21

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

inflammatory and oxidative stress factors, sonographic findings and symptom of depression, anxiety and stress in children with nonalcoholic fatty liver disease

Public title
Curcumin-piperine supplementation in children with none- alcoholic fatty liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children with non alcoholic fatty liver disease 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 Alanine aminotransferase level including HMG-COA reductase inhibitors, metformin
Age
From **10 years** old to **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be divided into intervention and control groups using block classified randomization. The following authoritative site will be used to allocate the intervention in the above-mentioned manner. https://www.sealedenvelope.com/simple-randomiser/v1/lists In this way, people are randomly divided into two groups of intervention and control using quadruple blocks based on age and sex. It is noteworthy that participants and outcome assessors will not be aware of patient grouping and will be blind to it.
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
2021-09-05, 1400/06/14
Ethics committee reference number
IR.MUI.RESEARCH.REC.1400.476

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
C-reactive protein
Timepoint
At the beginning of study - week 10
Method of measurement
Biochemical assessment

2

Description
Total antioxidant capacity
Timepoint
At the beginning of study - week 10
Method of measurement
Biochemical assessment

3

Description
Total oxidant status
Timepoint
At the beginning of study - week 10
Method of measurement
Biochemical assessment

4

Description
Oxidative stress index
Timepoint
At the beginning of study - week 10
Method of measurement
Biochemical assessment

Secondary outcomes

1

Description
Sonographic findings
Timepoint
At the beginning of study - week 10
Method of measurement
Liver ultrasonography

Intervention groups

1

Description
Intervention group: Take one capsule containing curcumin piperine daily (containing 500 mg curcumin extract and 5 mg piperine, Sami labs Ltd., India) for 10 weeks.
Category
Treatment - Drugs

2

Description
Control group: They will receive one placebo capsule (500 mg of maltodextrin, Sami labs Ltd., India) daily 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
Phone
+98 31 3386 6266
Email
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
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 21 8145 5618
Email
ethics@behdasht.gov.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
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
Gholamreza Askari
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Hezar-jerib Ave
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone

+98 31 3792 3171

Email

askari@mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Askari

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Hezar-jerib Ave

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3792 3171

Email

askari@mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

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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