

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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 beginning 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**

2021-09-05, 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

Isfahan

##### 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

Isfahan

##### 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

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##### 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**

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## Person responsible for updating data

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Esfahan University of Medical Sciences

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Gholamreza Askari

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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