

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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**

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###### **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**

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###### **Postal code**

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###### **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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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr. Gholamreza Askari

**Position**

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**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

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**Latest degree**

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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