

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### The effect of curcumin supplementation on lipid profile, liver enzymes, inflammatory factors and hepatic steatosis in patients with Nonalcoholic Fatty Liver Disease

#### Protocol summary

##### Study aim

The effect of curcumin supplementation on serum lipids, liver enzymes, inflammatory markers and hepatic steatosis in patients with nonalcoholic fatty liver.

##### Design

Randomized, double-blind, placebo-controlled

##### Settings and conduct

In this study, patients with non-alcoholic fatty liver referring to Taleqani Hospital, if they wish to participate in the study informed consent of them will be taken. After 12 to 14 hours of fasting, 5 cc of blood is taken to measure their blood serum concentrations of lipids, inflammatory factors and other serum biochemical parameters and kept in the freezer. Participants randomly using the divided randomly classified into two groups: supplement and placebo group.

##### Participants/Inclusion and exclusion criteria

Participants including major eligibility criteria: inclusion criteria: age 18 years and above; Concentrations of liver enzymes ALT and AST greater than 1.5 times normal; Evidence of nonalcoholic steatohepatitis in Fibroscan  
Exclusion criteria: Not continue to cooperation; Those less than 10% supplementation at the end of the sixth and twelfth week consume.

##### Intervention groups

Patients group supplement will be received daily 1.5 grams of curcumin for three months and Patients in the control group will be received placebo daily 1.5 grams.

##### Main outcome variables

Low Density Lipoprotein Cholesterol (LDL-C), High Density Lipoprotein Cholesterol (HDL-C), Triglyceride(TG), Total Cholesterol, Fasting Blood Sugar(FBS), Insulin, Homeostatic Model Assessment for Insulin Resistance(HOMA-IR), Aspartate Aminotransferase(ALT), Alanine Aminotransferase(ALT), TNF- $\alpha$ , hs-CRRP, IL-6, Liver Steatosis, Age, Sex, Smoking, Weight, Height, Waist Circumference, Hip Circumference, Waist to Hip

Ratio(WHR), Body Mass Index(BMI), Total energy intake, Total carbohydrate intake, Total fat intake, Total protein intake, Total fiber intake, Total SFA intake, Total MUFA intake, Total PUFA intake

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100524004010N24**

Registration date: **2018-05-14, 1397/02/24**

Registration timing: **retrospective**

Last update: **2018-05-14, 1397/02/24**

Update count: **0**

##### Registration date

2018-05-14, 1397/02/24

##### Registrant information

##### Name

Azita Hekmatdoost

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences,  
National Institute of Nutrition Research

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2293 0824

##### Email address

hekmat@sina.tums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

Vice Chancellor Of Research, Shahid Beheshti University  
Of Medical Sciences

##### Expected recruitment start date

2017-04-09, 1396/01/20  
**Expected recruitment end date**  
2017-08-11, 1396/05/20  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
The effect of curcumin supplementation on lipid profile, liver enzymes, inflammatory factors and hepatic steatosis in patients with Nonalcoholic Fatty Liver Disease

**Public title**  
The effect of curcumin supplementation on Nonalcoholic Fatty Liver Disease

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Age >18 years old Controlled Attenuation Parameter (CAP score)>263 Having a history of alcohol consumption less than 10 mg per day in women and less than 20 mg per day in men Absence of other acute and chronic diseases and disorders of the liver (hepatitis B, C, etc.), biliary disease, known autoimmune diseases, cancer and inherited disorders affecting liver condition (storage disease of iron, and copper. ...) Absence of Hypertension, cardio - vascular diseases, lung disease and kidney disease, cirrhosis and celiac disease Absence of pregnancy or lactation Athletes or hospitalization Not consume medications such as metformin, vitamin E and Ursodeoxycholic Acid (UDCA) Not consume hepatotoxic drugs such as phenytoin, tamoxifen and lithium and corticosteroids and methotrexate Not consume medications of antibiotics over a week during the study period or before entering it No history of weight loss surgery in the past year the 3-month weight loss program No history of hypothyroidism, Cushing's syndrome and diabetes Lack of gall bladder disease

**Exclusion criteria:**

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **50**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

Patients will be randomly assigned to receive curcumin or placebo.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The method use in this study to create a randomization process is simple randomization, so we utilize random number table. Beginning of the study, in order to observe the lack of a comprehension of researcher in each group, the canisters containing the capsules are coded by a person other than the researcher to A and B.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee Of Shahid Beheshti University Of Medical Sciences

**Street address**

Velenjak St. , Shahid Chamran Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1981619573

**Approval date**

2017-03-06, 1395/12/16

**Ethics committee reference number**

IR.SBMU.nnftri.13950106

**Health conditions studied**

**1**

**Description of health condition studied**

Nonalcoholic Fatty Liver Disease

**ICD-10 code**

(K75.8)

**ICD-10 code description**

Other specified inflammatory liver diseases

**Primary outcomes**

**1**

**Description**

Type of supplement

**Timepoint**

Begining and end of the study

**Method of measurement**

Data collection forms

## 2

### **Description**

LDL-C

### **Timepoint**

Beginning and end of the study

### **Method of measurement**

Enzymatic method using a kit

## 3

### **Description**

HDL-C

### **Timepoint**

Beginning and end of the study

### **Method of measurement**

Enzymatic method using a kit

## 4

### **Description**

TG

### **Timepoint**

Beginning and end of the study

### **Method of measurement**

Enzymatic method using a kit

## 5

### **Description**

Total Cholesterol

### **Timepoint**

Beginning and end of the study

### **Method of measurement**

Enzymatic method using a kit

## 6

### **Description**

AST

### **Timepoint**

Beginning and end of the study

### **Method of measurement**

Enzymatic method using a kit

## 7

### **Description**

ALT

### **Timepoint**

Beginning and end of the study

### **Method of measurement**

Enzymatic method using a kit

## 8

### **Description**

TNF- $\alpha$

### **Timepoint**

Beginning and end of the study

### **Method of measurement**

ELISA

## 9

### **Description**

hs-CRP

### **Timepoint**

Beginning and end of the study

### **Method of measurement**

ELISA

## 10

### **Description**

Cytokeratin-18

### **Timepoint**

Beginning and end of the study

### **Method of measurement**

ELISA

## 11

### **Description**

IL-6

### **Timepoint**

Beginning and end of the study

### **Method of measurement**

ELISA

## 12

### **Description**

Hepatic Steatosis

### **Timepoint**

Beginning and end of the study

### **Method of measurement**

Ultrasound

## **Secondary outcomes**

## 1

### **Description**

FBS

### **Timepoint**

Beginning and end of the study

### **Method of measurement**

Enzymatic method using a kit

## 2

### **Description**

Serum Insulin

### **Timepoint**

Beginning and end of the study

### **Method of measurement**

Radioimmunoassay

## 3

### **Description**

HOMA-IR

### **Timepoint**

Beginning and end of the study

### **Method of measurement**

Calculation

#### 4

**Description**

Ferritin

**Timepoint**

Beginning and end of the study

**Method of measurement**

ELISA

#### 5

**Description**

Uric Acid

**Timepoint**

Beginning and end of the study

**Method of measurement**

ELISA

#### 6

**Description**

Age

**Timepoint**

Beginning of the study

**Method of measurement**

Question

#### 7

**Description**

Sex

**Timepoint**

begining of the study

**Method of measurement**

observation

#### 8

**Description**

Smoking

**Timepoint**

Beginning of the study

**Method of measurement**

Questionare

#### 9

**Description**

Height

**Timepoint**

Beginning of the study

**Method of measurement**

Meter

#### 10

**Description**

Weight

**Timepoint**

Beginning and end of the study

**Method of measurement**

Balance

#### 11

**Description**

BMI

**Timepoint**

Beginning and end of the study

**Method of measurement**

Calculation

#### 12

**Description**

Total Calorie Intake

**Timepoint**

Beginning and end of the study

**Method of measurement**

Recall Questionare

#### 13

**Description**

Total Carbohydrate Intake

**Timepoint**

Beginning and end of the study

**Method of measurement**

Recall Questionare

#### 14

**Description**

Total Protein Intake

**Timepoint**

Beginning and end of the study

**Method of measurement**

Recall Questionare

#### 15

**Description**

Total Fat Intake

**Timepoint**

Beginning and end of the study

**Method of measurement**

Recall Questionare

#### 16

**Description**

Total Fiber Intake

**Timepoint**

Beginning and end of the study

**Method of measurement**

Recall Questionare

#### 17

**Description**

Total MUFA Intake

**Timepoint**

Beginning and end of the study

**Method of measurement**

Recall Questionare

## 18

### Description

Total PUFA Intake

### Timepoint

Beginning and end of the study

### Method of measurement

Recall Questionnaire

## 19

### Description

Total SFA Intake

### Timepoint

Beginning and end of the study

### Method of measurement

Recall Questionnaire

## Intervention groups

### 1

#### Description

Intervention group: 1.5 gram curcumin per day for 3 months

#### Category

Treatment - Other

### 2

#### Description

Control group: 1.5 gram maltodextrin per day for 3 months

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Taleqani Hospital

##### Full name of responsible person

Amir Sadeghi

##### Street address

Arabi Ave, Daneshjoo Blvd, Velenjak

##### City

Tehran

##### Province

Tehran

##### Postal code

1985711151

##### Phone

+98 21 2243 2560

##### Email

taleghanihospital@sbmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Dr. Afshin Zarghi

##### Street address

Arabi Ave, Daneshjoo Blvd, Velenjak

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

##### Phone

+98 21 23871

##### Email

info@sbmu.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Shahid Beheshti 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

Nutrition Faculty Of Shahid Beheshti University Of Medical Science

##### Full name of responsible person

Azita Hekmatdoost

##### Position

Associate Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nutrition

##### Street address

Hafezi Ave, Shahid Farahzadi Blvd, Shahrak Qarb

##### City

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##### Province

Tehran

##### Postal code

1985717443

##### Phone

+98 21 2237 6480

##### Fax

**Email**

A\_hekmat2000@yahoo.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Nutrition Faculty Of Shahid Beheshti University Of Medical Science

**Full name of responsible person**

Azita Hekmatdoost

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Hafezi Ave, Shahid Farahzadi Blvd, Shahrak Qarb

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1985717443

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A\_hekmat2000@yahoo.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Saeede Saadati

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

**Street address**

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۹۸۱۶۱۹۵۷۳

**Phone**

+98 21224325609

**Fax****Email**

s.saadati1992@gmail.com

**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Because the participant's informations should remain confidential.

**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