

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Impact of curcumin capsules on serum levels of pro-inflammatory, anti-inflammatory cytokines and cell adhesion molecules in Non-alcoholic fatty liver disease

#### Protocol summary

##### Summary

**Objectives:** The aim of this study will investigate impact of curcumin capsules on serum levels of pro-inflammatory/anti-inflammatory cytokines and adhesion molecules in Non-alcoholic fatty liver disease (NAFLD).  
**Design:** This randomized (by using random numbers table), double-blinded, placebo- controlled clinical trial in 80 NAFLD patients. **Setting and conduct:** patients with inclusion criteria: for participation of patients in the study will be diagnosed with MetS according to the Adult Treatment Panel (ATP) III criteria also inclusion criteria were diagnosis of NAFLD (grades 1- 3) according to liver ultrasonography. **Exclusion criteria** were pregnancy or breastfeeding, NAFLD secondary to alcohol consumption, smoking, consumption of hypoglycemic, hypolipidemic, and anti-inflammatory medications as well as any drug known to affect hepatic function, and the presence of hepatitis, coronary, renal, pulmonary, and thyroid diseases. **Eligible subjects** will be randomly divided into two treatment groups and control. **Interventions:** In the treatment group take curcumin (500 mg/day of an amorphous dispersion preparation comprising 70-mg curcuminoids) (n = 40) or placebo (n = 40). **The main outcome variables:** At the beginning and end of a month of blood samples for determination of pro-inflammatory/anti-inflammatory cytokines (IL-6, IL-8, TNF- $\alpha$ , IL-1, VEGF, IL-10, MCP-1, MCP-1) and adhesion molecules (L-selectin, P-selectin, E-selectin, ICAM-1 and VCAM-1).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201702209662N12**

Registration date: **2017-04-25, 1396/02/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-04-25, 1396/02/05

##### Registrant information

###### Name

Sedigheh Asgari

###### Name of organization / entity

Isfahan Cardiovascular Research Center ,Isfahan Cardiovascular Research institute , Physiology Re

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

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##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research of Isfahan Cardiovascular Research Center and Vice chancellor for research of Mashhad University of Medical Sciences

##### Expected recruitment start date

2016-10-22, 1395/08/01

##### Expected recruitment end date

2017-03-21, 1396/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Impact of curcumin capsules on serum levels of pro-inflammatory, anti-inflammatory cytokines and cell adhesion molecules in Non-alcoholic fatty liver disease

**Public title**

Impact of curcumin in Non-alcoholic fatty liver disease

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Adult subjects with symptoms of metabolic syndrome including waist circumference greater than 102 cm (male) or greater than 88cm (female); blood pressure greater than or equal 130/ 85 mmHg; triglycerides greater than 150 mg/dl; high-density lipoprotein cholesterol (HDL-C) less than 40 mg/d (males) or less than 50 mg/d (females); and fasting blood glucose greater than 100 mg/dL were screened for eligibility. Also inclusion criteria were diagnosis of NAFLD (grades 1-3) according to liver ultrasonography. Exclusion criteria: will be pregnancy or breastfeeding; NAFLD secondary to alcohol consumption; smoking, consumption of hypoglycemic; hypolipidemic; and anti-inflammatory medications as well as any drug known to affect hepatic function; and the presence of hepatitis; coronary; renal; pulmonary; and thyroid diseases

**Age**

From **18 years** old to **70 years** old

**Gender**

Both

**Phase**

1-2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan Cardiovascular Research Institute

**Street address**

Shahid Rahmani Alley, Third Moshtagh streets, After Shahid Chamran Hospital, Isfahan Cardiovascular Research Institute, Isfahan

**City**

Isfahan

**Postal code****Approval date**

2016-04-18, 1395/01/30

**Ethics committee reference number**

IR.MUI.REC.1394.110

**Health conditions studied****1****Description of health condition studied**

Nonalcoholic fatty liver disease (NAFLD)

**ICD-10 code**

K76.0

**ICD-10 code description**

Fatty (change of) liver, not elsewhere classified

**2****Description of health condition studied**

Other specified inflammatory liver diseases

**ICD-10 code**

K75.8

**ICD-10 code description**

Other specified inflammatory liver diseases

**Primary outcomes****1****Description**

L-selectin

**Timepoint**

Before and 8 weeks after intervention

**Method of measurement**

ELISA Kit

**2****Description**

E-selectin

**Timepoint**

Before and 8 weeks after intervention

**Method of measurement**

ELISA Kit

**3****Description**

p-selectin

**Timepoint**

Before and 8 weeks after intervention

**Method of measurement**

ELISA Kit

**4****Description**

V CAM-1

**Timepoint**

Before and 8 weeks after intervention

**Method of measurement**

ELISA Kit

## 5

### **Description**

I CAM-1

### **Timepoint**

Before and 8 weeks after intervention

### **Method of measurement**

ELISA Kit

## 6

### **Description**

IL-6

### **Timepoint**

Before and 8 weeks after intervention

### **Method of measurement**

ELISA Kit

## 7

### **Description**

IL-8

### **Timepoint**

Before and 8 weeks after intervention

### **Method of measurement**

ELISA Kit

## 8

### **Description**

IL-1

### **Timepoint**

Before and 8 weeks after intervention

### **Method of measurement**

ELISA Kit

## 9

### **Description**

IL-10

### **Timepoint**

Before and 8 weeks after intervention

### **Method of measurement**

ELISA Kit

## 10

### **Description**

TNF- $\alpha$

### **Timepoint**

Before and 8 weeks after intervention

### **Method of measurement**

ELISA Kit

## 11

### **Description**

VEGF

### **Timepoint**

Before and 8 weeks after intervention

### **Method of measurement**

ELISA Kit

## 12

### **Description**

MCP-1

### **Timepoint**

Before and 8 weeks after intervention

### **Method of measurement**

ELISA Kit

## **Secondary outcomes**

### 1

#### **Description**

Grade of fatty liver

#### **Timepoint**

Before and 8 weeks after intervention

#### **Method of measurement**

Ultrasonography

### 2

#### **Description**

BMI

#### **Timepoint**

Before and 8 weeks after intervention

#### **Method of measurement**

Kg/m<sup>2</sup>

## **Intervention groups**

### 1

#### **Description**

A number of curcumin capsules daily (500 mg) for 8 weeks

#### **Category**

Treatment - Drugs

### 2

#### **Description**

A number of placebo capsules daily (500 mg) for 8 weeks

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Isfahan Cardiovascular Research Institute

##### **Full name of responsible person**

Mahtab Keshvari

##### **Street address**

Shahid Rahmani Alley, Third Moshtagh streets, After Shahid Chamran Hospital, Isfahan Cardiovascular Research Institute, Isfahan

##### **City**

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice chancellor for research of Isfahan Cardiovascular Research Center

**Full name of responsible person**

Dr.Masoumeh Sadeghi

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Shahid Rahmani Alley, Third Moshtagh streets, After Shahid Chamran Hospital, Isfahan Cardiovascular Research Institute, Isfahan

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research of Isfahan Cardiovascular Research Center

**Proportion provided by this source****Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

### 2

#### Sponsor

**Name of organization / entity**

Vice chancellor for research of Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Mohsen Tafaghodi

**Street address**

Mashhad University of medical sciences, University ave .,Mashhad-Iran

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research of Mashhad University of Medical Sciences

**Proportion provided by this source****Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr.Amir Hossin Sahebkar

**Position**

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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

#### Contact

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*