

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- α , 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

+98 31 1335 9090

Email address

s_asgari@crc.mui.ac.ir

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- α

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/m²

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

Street address

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

City

Isfahan

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

City

Mashhad

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

Faculty Mashhad University of Medical Sciences

Other areas of specialty/work**Street address**

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

City

Mashhad

Postal code

9177899191

Phone

+98 51 3841 1538

Fax**Email**

SahebkarA@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan Cardiovascular Research Institute

Full name of responsible person

Dr. Sedigheh Asgary

Position

Faculty Isfahan Cardiovascular Research Institute

Other areas of specialty/work**Street address**

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

City

Isfahan

Postal code

۸۱۴۶۵۱۱۴۸

Phone

+98 31 3611 5313

Fax**Email**

sasgary@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Isfahan Cardiovascular Research Institute

Full name of responsible person

Mahtab Keshvari

Position

MS Research

Other areas of specialty/work**Street address**

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

City

Isfahan

Postal code

۸۱۴۶۵۱۱۴۸

Phone

+98 31 3611 5115

Fax**Email**

mahtabkeshvari87@yahoo.com

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