Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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-inflammatorycytokines(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
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Name of organization / entity
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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-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
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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