Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effects of curcumin plus piperine supplementation on cardiometabolic risk factors and fibroscan findings in patients with moderate-to-high hepatic steatosis : a randomized double blind placebo-controlled trial

Protocol summary

Study aim

The effects of curcumin plus piperine supplementation on cardiometabolic risk factors and fibroscan findings in patients with moderate-to-high hepatic steatosis : a randomized double blind placebo-controlled trial

Design

This is a randomized, placebo-controlled, double-blind parallel-group clinical trial. Sixty participants will randomly allocated to receive curcumin-piperine supplement per day (n = 30) or placebo (n = 30).

Settings and conduct

The present study is a double-blind, randomized, parallel clinical trial. The target population includes those with non-alcoholic fatty liver disease (NAFLD) with 2 and 3 grade referred to the Imam Musa Sadr Clinic who are diagnosed according to the sonography results by a Digestive and liver specialist. Split and study for12 weeks. Before and after the intervention, steatosis and fibrosis degree, serum HS-CRP level, liver enzyme, anthropocentric indices (body mass index and waist circumference), fasting blood sugar and blood pressure will be measured. To double-blind this study, all capsules were coded as A and B prior to study initiation

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participation in the study, Age 18-65 years, Evidence of NAFLD with 2 and 3 grade by sonography which previously diagnosed Exclusion criteria: Alcohol use, People with chronic diseases, liver diseases, biliary disorders, Use of the mentioned drugs within three months of study,weight loss.

Intervention groups

Intervention group a daily curcumin-piperine capsule(500 mg curcumin+ 5 mg piperine) and placebo group a daily corn starch capsule will receive after meal for 12 weeks.

Main outcome variables

TG; TC; HDL; LDL; Weight; BMI; Waist circumference; FBS; ALT; AST; Hepatic steatosis and fibrosis, Hs-CRP, BP

General information

Reason for update

Due to the prevalence of COVID-19 and the lack of patients with non-alcoholic steatohepatitis (NASH), the title of the project has changed.

Acronym

IRCT registration information

IRCT registration number: **IRCT20121216011763N47**
Registration date: **2020-05-14, 1399/02/25**
Registration timing: **prospective**

Last update: **2022-04-10, 1401/01/21**
Update count: **1**

Registration date

2020-05-14, 1399/02/25

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

2020-09-22, 1399/07/01

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of curcumin plus piperine supplementation on cardiometabolic risk factors and fibroscan findings in patients with moderate-to-high hepatic steatosis : a randomized double blind placebo-controlled trial

Public title

Effect of Curcumin-Piperine in moderate-to-high hepatic steatosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participation in the study Age 18-65 years Evidence indicating non alcoholic fatty liver disease (NAFLD) white grade 2 and 3 diagnosed with sonography.

Exclusion criteria:

Alcohol use People with heart , pulmonary and kidney diseases, hepatitis, cirrhosis, biliary and immune disorders, hypertension, diabetes, hypothyroidism and Cushing's syndrome Consumption of Metformin, Vitamin E, Orsodeoxycholic acid, Phenytoin, tamoxifen, Lithium, Corticosteroids and Methotrexate within three months of the study. Weight loss or bariatric surgery in recent years Pregnancy Supplement intolerance and unexpected adverse effects

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomly, based on the permuted block randomization method, using blocks of 4 that will be blocked based on gender variables and body mass index will be assigned to one of two curcumin and placebo groups.The enrolling participants, and assigning participants to the groups will carried out by a trained nutritionist. Researchers will not informed about randomization process until completion of data analyses.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double blind clinical trial (participant, researcher). The curcumin supplement and its placebo (identical from color, odor and shape) will be packaged in similar boxes, and the researcher and patients will not be informed of the contents of the packs until the end of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Institute for Medical Research Development (NIMAD)

Street address

Besat street

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۶۹۳۱۱۱

Approval date

2019-12-07, 1398/09/16

Ethics committee reference number

IR.NIMAD.REC.1398.306

Health conditions studied

1

Description of health condition studied

Non-alcoholic fatty liver disease (NAFLD)

ICD-10 code

R94.5

ICD-10 code description

Abnormal results of liver function studies

Primary outcomes

1

Description

Triglyceride (TG)

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Enzymatic method

2

Description
Total Cholesterol (TC)
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Enzymatic method

3

Description
Low density lipoprotein (LDL)
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Enzymatic method

4

Description
High density lipoprotein (HDL)
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Enzymatic method

5

Description
Weight
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Digital scale

6

Description
Waist Circumference (WC)
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Non-stretching tape measure

7

Description
Body mass index (BMI)
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Dividing the weight into kilograms by squared height by meter

8

Description
Aspartate aminotransferase (AST)
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Enzymatic photometric method

9

Description
Alanine aminotransferase (ALT)
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Enzymatic photometric method

10

Description
Hepatic steatosis and fibrosis
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Fibroscan

11

Description
Fasting blood sugar (FBS)
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Enzymatic

12

Description
blood pressure
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Sphygmomonometer

13

Description
Serum levels of High sensitive C-reactive protein (Hs-CRP)
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA) kits

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: A daily curcumin-piperine capsule(500 mg curcumin+ 5 mg piperine) will receive after meal for 12 weeks.
Category
Treatment - Other

2

Description

Control group: A daily placebo capsule(500 mg maltodextrin) will receive after meal for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Musa Sadr Clinic

Full name of responsible person

Gholamreza askari

Street address

Foroughi Ave

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8174673461

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+98 31 1792 2110

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askari@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjou

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Hezar Jarib

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Isfahan

Province

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81746-73461

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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

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

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Position

Student

Latest degree

Bachelor

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Associate professor

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Ph.D.

Other areas of specialty/work
Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
The collected deidentified for the primary outcome measure only will be shared

When the data will become available and for how long
12 months after publication

To whom data/document is available
Available for people working in academic institutions

Under which criteria data/document could be used
To conduct similar studies

From where data/document is obtainable
askari@mui.ac.ir

What processes are involved for a request to access data/document
The data will be sent to the person within two weeks after receiving the request and reviewing the request.

Comments