Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

The effect of Curcumin-Piperine supplementation on cardiometabolic factors, hepatic steatosis and fibrosis of fibroscan results and liver function in patients with non-alcoholic fatty liver disease: a randomized double-blind clinical trial

Protocol summary

Study aim

Determination of the effect of curcumin-piperine supplementation on cardiometabolic factors, hepatic steatosis and fibrosis of fibroscan results and liver function in patients with non-alcoholic fatty liver disease

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

In this study, patients with NAFLD will recruited from Imam Musa Sadr Clinic , Isfahan, Iran. Subjects will stratified according to gender. Random assignment will done by the use of table of random numbers. The enrolling participants, and assigning participants to the groups will carried out by a trained nutritionist.The curcumin-piperine supplement and its placebos will be packed in similar boxes, and the researcher and the patients will not be aware of the content of the pack until the end of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Tendency to participate in the study; People aged 18-65 years; Patients with Non-alcoholic fatty liver (grade 3-1) diagnosed by ultrasound Exclusion criteria: Pregnancy and lactation; Patients with Alcoholic Fatty Liver; Smoking; People with heart , pulmonary and kidney diseases, hepatitis, cirrhosis, biliary and immune disorders, hypertension, hypothyroidism and Cushing's syndrome; Consumption of lipid and glucose lowering medicine, Vitamin E, Vitamin D, Orsodeoxycholic acid, Phenytoin, Tamoxifen, Lithium, Corticosteroids and Methotrexate; Weight loss and bariatric surgery in the last year

Intervention groups

Individuals will randomly assigned to two groups to receive 500 mg/day curcumin-piperine supplement or placebo for 12 weeks.

Main outcome variables

TG; TC; HDL; LDL; Weight; BMI; Waist circumference; FBS; ALT; AST; Hepatic steatosis and fibrosis

General information

Reason for update

Given that underlying diseases such as metabolic syndrome and diabetes contribute to the development of non-alcoholic fatty liver disease by disrupting metabolic factors, a percentage of patients with non-alcoholic fatty liver disease have diabetes. As a result, based on the advice of the consulting physician, it was suggested that the presence of diabetes be excluded from the study exclusion criteria in order to make the design and its results closer to the community.

Acronym

IRCT registration information

IRCT registration number: **IRCT20121216011763N42**
Registration date: **2020-01-10, 1398/10/20**
Registration timing: **registered_while_recruiting**

Last update: **2025-06-12, 1404/03/22**
Update count: **1**

Registration date

2020-01-10, 1398/10/20

Registrant information

Name

Gholamreza Askari

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-21, 1398/09/30

Expected recruitment end date

2020-04-19, 1399/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Curcumin-Piperine supplementation on cardiometabolic factors, hepatic steatosis and fibrosis of fibroscan results and liver function in patients with non-alcoholic fatty liver disease: a randomized double-blind clinical trial

Public title

Effect of Curcumin-Piperine in Fatty Liver

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Tendency to participate in the study People aged 18-65 years Patients with Non-alcoholic fatty liver (grade 3-1) diagnosed by ultrasound

Exclusion criteria:

Pregnancy and lactation Patients with Alcoholic Fatty Liver Smoking People with heart , pulmonary and kidney diseases, hepatitis, cirrhosis, biliary and immune disorders, hypertension, hypothyroidism and Cushing's syndrome Consumption of lipid and glucose lowering medicine, Vitamin E, Vitamin D, Orsodeoxycholic acid, Phenytoin, Tamoxifen, Lithium, Corticosteroids and Methotrexate Weight loss and bariatric surgery in the last year

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 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 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

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezarjarib Ave., Isfahan University of Medical Sciences

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2019-11-05, 1398/08/14

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.462

Health conditions studied

1

Description of health condition studied

Nonalcoholic fatty liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

TG

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Enzymatic method

2

Description

TC

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Enzymatic method

3

Description

HDL

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Enzymatic method

4

Description

LDL

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

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

non-stretching tape measure

7

Description

BMI

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Dividing the weight into kilograms by squared height by meter

8

Description

ALT

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Enzymatic photometric method

9

Description

AST

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

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A daily curcumin-piperine capsule(500 mg curcumin+ 5 mg piperine) will recive after meal for 12 weeks.

Category

Treatment - Other

2

Description

Control group: A daily placebo capsule(500 mg lactose) will recive 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

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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sh_haghjoo@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
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
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Gholamreza Askari
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Associate professor
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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 send as soon as possible, after receiving the request.

Comments