

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Effect of phytosomal curcumin on lipid profile, fasting blood glucose, anthropometric indices, hepatic function and degree of steatosis, and liver fibrosis measured by fibroscan in non-alcoholic fatty liver patients: a double-blind clinical trial

Protocol summary

Study aim

Determine the supplementary effect of phytosomal curcumin on lipid profile (Tch, TG, LDL, HDL), fasting blood glucose (FBS), anthropometric indices (weight, height, waist circumference, BMI), fibroscan findings, and liver function (ALT, AST) in non-alcoholic fatty liver disease.

Design

A randomized, controlled, double-blind, placebo-controlled clinical trial

Settings and conduct

Patients with fatty liver in Imam Musa Sadr Clinic will be included in the study if they meet all criteria and obtain written consent. The samples will be randomly divided into intervention and placebo groups and will be studied for 12 weeks. Before and after the intervention lipid profile, blood glucose, anthropometric indices, liver enzymes and degree of steatosis and liver fibrosis 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 participate in the study, age 18-65 years, non-alcoholic fatty liver Exclusion criteria: Pregnancy and lactation, chronic disease, use of drugs affecting the liver, weight loss and bariatric surgery

Intervention groups

The intervention group (n=30) will receive one 250 mg phytosomal curcumin capsule daily for 12 weeks. The control group (n=30) will receive one placebo (250 mg maltodextrin) daily for 12 weeks.

Main outcome variables

Primary outcome: Liver enzymes (ALT, AST), degree of fibrosis, and liver steatosis Secondary outcome: HDL, LDL, Tch, TG, FBS, anthropometric indices (height, weight, waist circumference, BMI)

General information

Reason for update

Using phytosomal curcumin instead of curcumin Using a dose of 250 mg of phytosomal curcumin instead of 500 mg of curcumin.

Acronym

IRCT registration information

IRCT registration number: **IRCT20121216011763N39**

Registration date: **2019-11-26, 1398/09/05**

Registration timing: **prospective**

Last update: **2022-07-26, 1401/05/04**

Update count: **1**

Registration date

2019-11-26, 1398/09/05

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

2020-04-20, 1399/02/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of phytosomal curcumin on lipid profile, fasting blood glucose, anthropometric indices, hepatic function and degree of steatosis, and liver fibrosis measured by fibroscan in non-alcoholic fatty liver patients: a double-blind clinical trial

Public title
The effect of phytosomal curcumin on fatty liver

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study age 18-65 years
Non-alcoholic fatty liver (Grade 1-3) diagnosed by previous ultrasound
Exclusion criteria:
Pregnancy and lactation Alcoholic fatty liver disease
Tobacco consumption Heart, Lung and Kidney Diseases, Hepatitis, Cirrhosis, Biliary and Immune Disorders, Diabetes, Cushing's Syndrome Intake of lipid and glucose lowering drugs, Vitamin E and D, orthoedoxic 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 phytosomal curcumin and placebo groups. The enrolling participants, and assigning participants to the groups will be carried out by a trained nutritionist. Researchers will not be 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 phytosomal 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

Kurosh Building, Shahid Tavakoli Alley, Kave St., Isfahan, Iran

City

Esfahan

Province

Isfahan

Postal code

8189164351

Approval date

2019-11-19, 1398/08/28

Ethics committee reference number

1398.461

Health conditions studied

1

Description of health condition studied

Non-alcoholic fatty liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Degree of liver fibrosis

Timepoint

Before intervention, end of intervention

Method of measurement

Fibroscan device

2

Description

Degree of liver steatosis

Timepoint

Before intervention, end of intervention

Method of measurement

Fibroscan device

3

Description

Alkaline amino transferase

Timepoint

Before intervention, end of intervention

Method of measurement

Enzymatic photometric

4

Description

Aspartate amino transferase

Timepoint

Before intervention, end of intervention

Method of measurement

Enzymatic photometric

Secondary outcomes

1

Description

TG

Timepoint

Before intervention, end of intervention

Method of measurement

Enzymatic

2

Description

Tch

Timepoint

Before intervention, end of intervention

Method of measurement

Enzymatic

3

Description

HDL

Timepoint

Before intervention, end of intervention

Method of measurement

Enzymatic

4

Description

LDL

Timepoint

Before intervention, end of intervention

Method of measurement

Fried Wald Equation equation

5

Description

FBS

Timepoint

Before intervention, end of intervention

Method of measurement

Enzymatic

6

Description

Weight

Timepoint

Before intervention, end of intervention

Method of measurement

Digital scale

7

Description

Waist

Timepoint

Before intervention, end of intervention

Method of measurement

Meters irreversible

8

Description

BMI

Timepoint

Before intervention, end of intervention

Method of measurement

Body Mass Index Formula

Intervention groups

1

Description

Intervention group: phytosomal curcumin, 250 mg oral capsule, once daily for 12 weeks

Category

Treatment - Other

2

Description

Control group: Placebo (maltodextrin) 250 mg orally, once daily 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 Street

City

esfahan

Province

Isfahan

Postal code
81746-73461
Phone
+98 31 3668 1378
Fax
+98 31 3668 1378
Email
Askari@mui.ac.ir

Isfahan
Postal code
8174673461
Phone
+98 31 3888 0048
Email
sh_haghjoo@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo
Street address
Hezar Jarib Ave, Isfahan University of Medical Sciences
City
Isfahan
Province
Isfahan
Postal code
81746-73461
Phone
+98 31 3668 8138
Email
sh_haghjoo@med.mui.ac.ir

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

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

The University of medical sciences Esfahan

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
Specialist
Other areas of specialty/work
Nutrition
Street address
Hezarjarib Ave
City
Esfahan
Province
Isfahan
Postal code
81746-73461
Phone
+98 31 3668 1378
Email
askari@mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Askari
Position
Associate professor

2

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo
Street address
Hezargrib Ave
City
Esfahan
Province

Latest degree
Specialist
Other areas of specialty/work
Nutrition
Street address
Hezarjarib Ave
City
Esfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 1792 2110
Email
askari@mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Askari
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Nutrition
Street address
Hezarjarib St
City
Esfahan
Province
Isfahan
Postal code
81746-73461
Phone

+98 31 1792 2110

Fax

+98 31 1792 2199

Email

askari@mui.ac.ir

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