Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Sep 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)
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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 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 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

Isfehan

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
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Sponsors / Funding sources

1

Sponsor
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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

2

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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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
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
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Person responsible for updating data

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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