Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Calebin-A supplementation on cardiometabolic risk factors, liver function tests, sonographic findings, and quality of life among patients with metabolic dysfunction-associated steatotic liver disease (MASLD): a double-blind randomized controlled clinical trial

Protocol summary

Study aim

Determination and comparison of the effects of Calbin A supplementation on cardiometabolic indices, liver function tests, ultrasonographic findings, and quality of life in patients with metabolic dysfunction–associated steatotic liver disease (MASLD) before and after the intervention.

Design

Clinical trial study with a control group, with two arm parallel-group, double-blind, randomized, phase 3 on 90 patients. For randomization, the block method (blocks of 4) and the site https://sealedenvelope.com/simple-randomiser/v1) will be used.

Settings and conduct

This clinical trial will be conducted among patients with MASLD attending a gastroenterology and hepatology subspecialty clinic. Calbin A supplement and placebo will be provided to participants in completely identical packaging for 12 weeks. Both the participants and the investigator will be blinded to the type of intervention.

Participants/Inclusion and exclusion criteria

Adult patients aged 18–65 years diagnosed with MASLD (hepatic steatosis plus at least one of the five metabolic dysfunction criteria) and a FIB-4 index > 1.3.

Intervention groups

The intervention group will receive two Calbin A capsules daily (each capsule containing 25 mg of Calbin A plus 5 mg of piperine), and the control group will receive two placebo capsules daily (each capsule containing 25 mg of maltodextrin plus 5 mg of piperine) for 12 weeks.

Main outcome variables

Before and after the intervention, serum liver enzymes (ALT, AST, ALP, and GGT), inflammatory markers (CRP and IL-6), oxidative stress indices (MDA, TAC, and SOD), and liver functional indices (FLI, FIB-4, and APRI) will be assessed as primary outcomes. Secondary outcomes will include glycemic indices, lipid profile, hepatic ultrasonographic findings, quality of life score, sleep quality score, depression, anxiety and stress scores, and mean anthropometric indices.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201129049534N12**
Registration date: **2026-04-13, 1405/01/24**
Registration timing: **prospective**

Last update: **2026-04-13, 1405/01/24**
Update count: **0**

Registration date

2026-04-13, 1405/01/24

Registrant information

Name

Mohammad bagherniya

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 3183

Email address

bagherniya@nutr.mui.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-04-21, 1405/02/01

Expected recruitment end date
2026-08-23, 1405/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Calebin-A supplementation on cardiometabolic risk factors, liver function tests, sonographic findings, and quality of life among patients with metabolic dysfunction-associated steatotic liver disease (MASLD): a double-blind randomized controlled clinical trial

Public title
The effect of Calebin-A supplementation in patients with metabolic dysfunction-associated steatotic liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 80 years Patients with MSLD (hepatic steatosis and one of the 5 factors of metabolic disorder) based on the confirmation of a radiologist and gastroenterologist. Having a FIB-4 index higher than 1.3 using lab data related to maximum a month ago Consent of the patient to participate in the study
Exclusion criteria:
Alcohol consumption of more than 30 gr/day in men and more than 20 gr/day in women Patients taking ursodeoxycholic acid, phenytoin, tamoxifen, lithium, corticosteroids, and methotrexate Taking vitamin E, omega-3, and probiotic supplements within the past 3 months Pregnancy and breastfeeding Uncontrolled or insulin-dependent diabetes Patients with liver cirrhosis, hepatitis, bile duct obstruction, immune system, Cushing's syndrome, cancer, and iron and copper storage disorders Weight loss diet in the last 3 months or weight loss surgery in the last year Starting a new medication or changing the dosage of previous medications associated with hepatic steatosis The patient's unwillingness to continue participating in the study Occurrence of any adverse events
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomize, stratified block randomization using blocks of 4 will be used. Also, matching will be done based on BMI (<25 and >25). For randomization using the site (https://sealedenvelope.com/simple-randomiser/v1) after determining the number of blocks and BMI (as variable based on which matching will be performed), all The blocks will be specified along with the type of intervention and the order of allocation of the intervention. The random allocation list of patients will be in the sole possession of an individual outside the plan.
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to conduct this research in a double-blind manner, before the study begins, all relevant capsules are coded as A and B by someone other than the researcher, so that the researcher is unaware of the type of capsules received by both groups. In this way, participants and outcome assessors will not be aware of the patient grouping and will be blinded to it.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Medicine - Isfahan University of Medical Sciences
Street address
School of Nutrition and Food Sciences, Isfahan University of Medical Sciences, Hezar-jerib Avenue
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2026-02-18, 1404/11/29
Ethics committee reference number
IR.MUI.MED.REC.1404.465

Health conditions studied

1

Description of health condition studied
Metabolic dysfunction associated steatotic liver disease
ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Alanine Aminotransferase (ALT)

Timepoint

Before and after intervention

Method of measurement

Commercial diagnostic kit

2

Description

Aspartate Aminotransferase (AST)

Timepoint

Before and after intervention

Method of measurement

Commercial diagnostic kit

3

Description

Alkaline Phosphatase (ALP)

Timepoint

Before and after intervention

Method of measurement

Commercial diagnostic kit

4

Description

Gamma-Glutamyl Transferase (GGT)

Timepoint

Before and after intervention

Method of measurement

Commercial diagnostic kit

5

Description

C reactive Protein (CRP)

Timepoint

Before and after intervention

Method of measurement

ELISA test

6

Description

Interleukin-6 (IL-6)

Timepoint

Before and after intervention

Method of measurement

ELISA test

7

Description

Malondialdehyde (MDA)

Timepoint

Before and after intervention

Method of measurement

ELISA test

8

Description

Total antioxidant capacity (TAC)

Timepoint

Before and after intervention

Method of measurement

ELISA test

9

Description

Superoxide dismutase (SOD)

Timepoint

Before and after intervention

Method of measurement

ELISA test

10

Description

Fatty liver index

Timepoint

Before and after intervention

Method of measurement

Based on the standard formula

11

Description

Aspartate aminotransaminase-to-platelet ratio index

Timepoint

Before and after intervention

Method of measurement

Based on the standard formula

12

Description

Fibrosis-4 index

Timepoint

Before and after intervention

Method of measurement

Based on the standard formula

Secondary outcomes

1

Description

fasting blood sugar (FBS)

Timepoint

Before and after intervention

Method of measurement

enzymatic colorimetric assay

2

Description
Fasting Insulin
Timepoint
Before and after intervention
Method of measurement
enzyme immunoassay

3

Description
Homeostasis model assessment-estimated insulin resistance (HOMA-IR)
Timepoint
Before and after intervention
Method of measurement
fasting insulin (mIU/mL) ×fasting blood glucose (mg/dL)/405

4

Description
total cholestrol
Timepoint
Before and after intervention
Method of measurement
Commercial diagnostic kit

5

Description
High-Density Lipoprotein
Timepoint
Before and after intervention
Method of measurement
Commercial diagnostic kit

6

Description
Low-Density Lipoprotein
Timepoint
Before and after intervention
Method of measurement
Commercial diagnostic kit

7

Description
Triglyceride
Timepoint
Before and after intervention
Method of measurement
Commercial diagnostic kit

8

Description
Fatty liver grade based on ultrasound
Timepoint
Before and after intervention
Method of measurement
ultrasound

9

Description
Quality of life
Timepoint
Before and after intervention
Method of measurement
Short Form Health Survey (SF-36)

10

Description
Sleep Quality
Timepoint
Before and after intervention
Method of measurement
Pittsburgh Sleep Quality Index

11

Description
Depression, anxiety and stress
Timepoint
Before and after intervention
Method of measurement
Depression anxiety stress scales-21 (DASS-21)

12

Description
Body mass index
Timepoint
Before and after intervention
Method of measurement
weight/ (height)2

13

Description
Waist circumference
Timepoint
Before and after intervention
Method of measurement
Using a non-elastic tape measure, without applying any pressure, approximately 0.1 cm at the narrowest part of the waist (at the end of a natural exhalation) in a standing position.

Intervention groups

1

Description
Intervention group: they will receive two Calebin A capsules daily (each capsule containing 25 mg of Calebin A plus 5 mg of piperine, produced by Sami Lab, India) for 12 weeks.
Category
Treatment - Drugs

2

Description

Control group: they will receive two placebo capsules daily (each capsule containing 25 mg of maltodextrin plus 5 mg of piperine, produced by Sami Lab, India) for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Hajar Heidari

Street address

Soffe Boulevard

City

Isfahan

Province

Isfehan

Postal code

8174675731

Phone

+98 31 3792 3164

Email

h.heidari72@ymail.com

2

Recruitment center

Name of recruitment center

Private Clinic of Dr. Mehdi Kazemi, Gastroenterology and Hepatology Subspecialist

Full name of responsible person

Hajar Heidari

Street address

Chaharbagh Bala Street

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Phone

+98 31 3792 3164

Email

h.heidari72@ymail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Behruz Ataei

Street address

Hezar-jerib Ave

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Phone

+98 21 8145 5618

Email

ethics@behdasht.gov.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

Full name of responsible person

Mohammad Bagherniya

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Hezar-jerib Ave

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Phone

+98 31 3792 3154

Email

bagherniya@nutr.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mohammad Bagherniya

Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Hezar-jerib Ave
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 3154
Email
bagherniya@nutr.mui.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad Bagherniya
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Hezar-jerib Ave
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 3154
Email
bagherniya@nutr.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Information about the study will be published after the individuals are not identified and the project is completed.
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
Only for researchers working in academic and scientific institutions
Under which criteria data/document could be used
For further analysis
From where data/document is obtainable
Dr. Mohammad Bagherniya email: bagherniya@nutr.mui.ac.ir
What processes are involved for a request to access data/document
After reviewing the request and making it fully clear about the purposes of using the data, the data will be provided.
Comments