Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Investigating the therapeutic effect of curcumin-peperin supplementation on metabolic syndrome, and liver fibrosis and steatosis indicators in bariatric surgery candidates: a randomized controlled trial.

Protocol summary

Study aim

Determining the therapeutic effects of curcumin-piperine supplementation on the indicators of metabolic syndrome, and liver fibrosis and steatosis in patients who are candidates for bariatric surgery.

Design

A controlled, parallel-group, triple-blind, randomized, phase 2 clinical trial on 110 patients. For randomization, special randomization sites such as sealed envelope are used.

Settings and conduct

A three-way blind controlled study will be conducted on bariatric surgery candidates with inclusion criteria, by giving a capsule containing 500 mg of curcumin and 5 mg of peprine to the intervention group and a placebo to the control group, for 8 weeks.

Participants/Inclusion and exclusion criteria

Patients with morbid obesity referred to the bariatric surgery clinic and met the inclusion criteria Entry requirements - Patients with morbid obesity and candidates for bariatric surgery in the age range of 18 to 65 years - Diagnosis of metabolic syndrome based on tests -Diagnosis of metabolically dysfunction-associated fatty liver disease (MASLD) through ultrasound, biochemical and clinical analyses Willingness to cooperate in the project and No allergy to curcumin or turmeric Non-entry conditions - Regular consumption of multivitamin-mineral supplements and consumption of herbal extracts such as silymarin during the last 3 months - Diagnosed pathological conditions effective on the body - History of gastrointestinal diseases, autoimmunity and various malignancies

Intervention groups

Patients with morbid obesity referred to the bariatric surgery clinic and met the inclusion criteria

Main outcome variables

The amount of changes in metabolic syndrome indicators: anthropometric analysis, biochemical analysis (FBS, HbA1c, Insulin, TG, LDL, HDL), systolic and diastolic blood pressure and Examining changes in the degree of hepatic steatosis or fibrosis

General information

Reason for update

Following approval of the changes to the proposal by the Research Committee of the Clinical Nutrition Department of Mashhad University of Medical Sciences, this update was made based on the amendment to the proposal.

Acronym

IRCT registration information

IRCT registration number: **IRCT20231116060076N1**
Registration date: **2023-11-30, 1402/09/09**
Registration timing: **prospective**

Last update: **2025-06-01, 1404/03/11**
Update count: **2**

Registration date

2023-11-30, 1402/09/09

Registrant information

Name

Mohadeseh Hassan zadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3882 7034

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hasanzadehm4001@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-11, 1402/09/20

Expected recruitment end date

2024-09-21, 1403/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the therapeutic effect of curcumin-peperin supplementation on metabolic syndrome, and liver fibrosis and steatosis indicators in bariatric surgery candidates: a randomized controlled trial.

Public title

Investigating the therapeutic effect of curcumin-peperin supplementation on metabolic syndrome, and liver fibrosis and steatosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with morbid obesity and candidates for bariatric surgery in the age range of 18 to 65 years Diagnosis of metabolic syndrome by a specialist physician based on biochemical and clinical analyses Diagnosis of metabolically dysfunction–associated fatty liver disease (MASLD) through ultrasound, biochemical and clinical analyses by a specialist physician Willingness to cooperate in the project No known allergies to curcumin or turmeric

Exclusion criteria:

Regular consumption of multivitamin-mineral supplements, antioxidants, and omega-3 supplements in amounts exceeding the daily requirement, probiotic supplements, and consumption of herbal extracts such as silymarin during the past 3 months. Diagnosed pathological conditions affecting the liver such as types of viral hepatitis and liver transplantation History of gastrointestinal diseases, organ failure, thyroid disorders, kidney diseases, autoimmune diseases, severe mental diseases and types of malignancy.

Age

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

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization with blocks of 4 and 6 will be done using special randomization sites such as sealed envelopes. After specifying the codes, each code is written separately on a sheet. Each sheet is placed in a separate envelope or folded and glued in such a way that it cannot be seen inside (allocation concealment). After obtaining informed consent, a sheet will be removed from each qualified patient and according to the code written in it, people will be placed in two study groups.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The patient receives the drug (intervention or control group) in sealed envelopes that are coded. Coding is done by one of the collaborators of the project and the patient, researcher and analyst are blinded.

Placebo

Used

Assignment

Parallel

Other design features

In this study, food intake using a 24-hour food recall questionnaire and physical activity using the international IPAQ questionnaire will be examined as confounding variables before the intervention and 6 months after surgery.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Qureshi Building, University Street, Mashhad, Khorasan Razavi

City

mashhad

Province

Razavi Khorasan

Postal code

۱۳۹۴۴ ۹۱۳۸۸

Approval date

2023-09-23, 1402/07/01

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1402.318

Health conditions studied

1

Description of health condition studied

Metabolic syndrome, liver fibrosis and steatosis

ICD-10 code

E88.8, K74

ICD-10 code description

Metabolic syndrome, Hepatic fibrosis, Hepatic steatosis,

Primary outcomes

1

Description
Fasting plasma glucose
Timepoint
Measurements will be taken at the beginning of the study (before the intervention), at the end of the intervention, and 6 months after surgery.
Method of measurement
Blood test using a laboratory assay

2

Description
2. Triglyceride
Timepoint
Measurements will be taken at the beginning of the study (before the intervention), at the end of the intervention, and 6 months after surgery.
Method of measurement
Blood test using a laboratory assay

3

Description
High Density Lipoprotein (HDL)
Timepoint
Measurements will be taken at the beginning of the study (before the intervention), at the end of the intervention, and 6 months after surgery.
Method of measurement
Blood test using a laboratory assay

4

Description
Blood Pressure
Timepoint
Measurements will be taken at the beginning of the study (before the intervention), at the end of the intervention, and 6 months after surgery.
Method of measurement
Mercury sphygmomanometer

5

Description
Anthropometric measurements
Timepoint
Measurements will be taken at the beginning of the study (before the intervention), at the end of the intervention, and 6 months after surgery.
Method of measurement
Height will be measured without shoes, with an accuracy of 0.5 cm, using a caliper. Weight, BMI, and waist-to-hip ratio will be measured using a bioelectrical impedance analyzer.

6

Description
Degree of hepatic steatosis or fibrosis
Timepoint
Measurements will be taken at the beginning of the study (before the intervention), at the end of the intervention, and 6 months after surgery.
Method of measurement
Liver elastography will be performed before the intervention and 6 months after surgery. Also, a liver biopsy will be performed at the end of the intervention (during surgery).

Secondary outcomes

1

Description
Liver enzymes (ALT, AST, ALP)
Timepoint
All variables will be measured at the beginning of the study (before the intervention), at the end of the intervention, and 6 months after surgery.
Method of measurement
Blood test using a laboratory assay

2

Description
Checking insulin resistance based on the HOMA-IR formula
Timepoint
All variables will be measured at the beginning of the study (before the intervention), at the end of the intervention, and 6 months after surgery.
Method of measurement
It will be measured by collecting a fasting blood sample at any time point and measuring fasting blood insulin and glucose levels using the formula HOMA-IR = [Fasting Glucose (mg/dL) x Fasting Insulin (mU/L)] / 405.

Intervention groups

1

Description
Intervention group: includes 55 morbidly obese patients who are candidates for bariatric surgery and who meet the study entry criteria, who will be given a daily supplement containing 500 mg of curcumin and 5 mg of peprine for 8 weeks.
Category
Treatment - Drugs

2

Description
Control group: It includes 55 patients with morbid obesity and candidates for bariatric surgery who meet the inclusion criteria and will be given a placebo daily for 8 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Outpatient bariatric surgery clinic of Imam Reza Hospital

Full name of responsible person
Reza Rezvani

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Imam Reza Hospital, Imam Reza Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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?
Yes

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Mohadeseh Hassan zadeh

Position
PhD candidate

Latest degree
Master

Other areas of specialty/work
Nutrition

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available