Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Determination of the Effect of Functional Oral Powder Enriched with Curcumin, Probiotics, and their Combination on Cardiometabolic Indices in Patients with Metabolic Syndrome with Overweight or Obesity: a Randomized, Double-blinded, Controlled Clinical Trial

Protocol summary

Study aim
The aim of this study is to evaluate the effect of oral powder enriched with curcumin and probiotics on cardiometabolic indices of patients with metabolic syndrome

Design
A parallel randomized double-blind controlled clinical trial of 124 patients. Block randomization with a fixed block size of 4 will be done

Settings and conduct
Patients with metabolic syndrome are referred to the Nutrition Clinic of Imam Reza Clinic, Shiraz, and are randomly divided into 4 study groups. The informed consent form, demographic information, international physical activity questionnaire (IPAQ), and 3-day food record are completed for all individuals before and after the study. Anthropometric measurements and measurements of the lipid profile are performed before and after the study. The appearance of the intervention powders is quite similar. The researcher and all participants will be blinded to the intervention and random allocation. Laboratory evaluations will be done in the nutrition laboratory of the Faculty of Nutrition and Food Sciences, Shiraz University of Medical Sciences, Shiraz, Iran.

Participants/Inclusion and exclusion criteria
Inclusion criteria: people 30 to 65 years old with metabolic syndrome. Exclusion criteria: pregnant and lactating people and people with kidney, liver, systemic, metabolic, endocrine, and cardiovascular diseases except diabetes, dyslipidemia, and blood pressure.

Intervention groups
Group 1 receives functional curcumin-enriched oral powder. Group 2 receives the functional probiotics-enriched oral powder. Group 3 receives the functional oral powder enriched with curcumin and probiotics. Group 4 receives the placebo oral powder.

Main outcome variables
Cardiometabolic indices:Atherogenic Index of Plasma = AIP Atherogenic Coefficient = AC Castelli Risk Index I Castelli Risk Index II

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220315054290N2**
Registration date: **2022-12-07, 1401/09/16**
Registration timing: **prospective**

Last update: **2022-12-07, 1401/09/16**
Update count: **0**

Registration date
2022-12-07, 1401/09/16

Registrant information

Name
Farzaneh Mohammadi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-22, 1401/10/01

Expected recruitment end date
2023-03-20, 1401/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Determination of the Effect of Functional Oral Powder Enriched with Curcumin, Probiotics, and their Combination on Cardiometabolic Indices in Patients with Metabolic Syndrome with Overweight or Obesity: a Randomized, Double-blinded, Controlled Clinical Trial

Public title
Investigation of the Effect of Oral Powder Enriched with Curcumin and Probiotics on Cardiometabolic Indices of Patients with Metabolic Syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age: 30-60 years old Metabolic syndrome patients are diagnosed based on the Adult Treatment Panel III (ATP III) criterion Consent to participate in the study
Exclusion criteria:
Pregnancy Lactation Metabolic, endocrine, and cardiovascular diseases except diabetes, dyslipidemia, and hypertension
Age
From **30 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **124**
Randomization (investigator's opinion)
Randomized
Randomization description
Before beginning the study, an outsider who is familiar with the randomization method prepares 4 blocks of random blocks, then randomly identifies the sequences and groups them in a closed envelope, named A, B, C, and D. After the individuals enter the study, the sealed envelopes containing the assigned group of participants will be opened for each participant based on the sequence determined by the person outside the study. Block randomization works by randomizing participants within blocks such that an equal number is assigned to each treatment. Allocation proceeds by randomly selecting one of the orderings and assigning the next block of participants to study groups according to the specified sequence. Furthermore, the block size must be divisible by the number of study groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
The appearance of the beverage powders and sachets in which they are packaged are quite similar. The sachets will be named with the Latin letters A, B, C, and D. In the clinical phase of the study, the random allocation sequence is done with the same letters. Therefore, the researcher and all participants will be blinded to the intervention.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Sciences, Zand Ave
City
Shiraz
Province
Fars
Postal code
7134814336
Approval date
2022-09-11, 1401/06/20
Ethics committee reference number
IR.SUMS.SCHEANUT.REC.1401.099

Health conditions studied

1

Description of health condition studied
Metabolic Syndrome
ICD-10 code
E88.81
ICD-10 code description
Metabolic syndrome

Primary outcomes

1

Description
Atherogenic Index of Plasma (AIP)
Timepoint
Before the study and 8 weeks after the start of the study
Method of measurement

AIP = log (TG/HDL - C)

2

Description
Atherogenic Coefficient = AC
Timepoint
Before the study and 8 weeks after the start of the study
Method of measurement
AC = (TC − HDL - C)/HDL - C

3

Description
Castelli Risk Index I
Timepoint
Before the study and 8 weeks after the start of the study
Method of measurement
Castelli risk index I = TC/HDL - C

4

Description
Castelli Risk Index II
Timepoint
Before the study and 8 weeks after the start of the study
Method of measurement
Castelli risk index II = LDL - C/HDL - C

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group will receive a daily oral powder enriched with 1 gram of curcumin for 8 weeks. Curcumin powder will be supplied by Karen Company.
Category
Treatment - Other

2

Description
The second intervention group will receive 10 to 9 CFU-enriched oral powders (Lactobacillus rhamnosus and Lactobacillus acidophilus) daily for 8 weeks. Probiotics will be provided by Parsi Lact Company.
Category
Treatment - Other

3

Description
The third intervention group will receive daily oral powder enriched with 1 gram of curcumin and 10 to 9 CFU probiotics for 8 weeks. Curcumin will be supplied by Karen Company and probiotics will be supplied by Parsi Lact Company.
Category
Treatment - Other

4

Description
The control group will receive placebo oral powder daily for 8 weeks. Placebo powder will be supplied by Parsi Lact Company.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Clinic
Full name of responsible person
Mohammad Hassan Eftekhari
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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memarpour@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Farzaneh Mohammadi

Position
PhD Candidate

Latest degree
Master

Other areas of specialty/work
Nutrition

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Person responsible for scientific inquiries

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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