Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Production of Functional Oral Powder Enriched with Curcumin, Probiotics, and their Combination and Determination of their Effect on Appetite, Leptin, and Ghrelin Hormones and Some Anthropometric Indices in Patients with Metabolic Syndrome with Overweight or Obesity: a Randomized Double-Blind 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 appetite, leptin and ghrelin hormones, and some anthropometric 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 Imam Reza Clinic and are randomly divided into 4 study groups. The informed consent form, demographic information, physical activity (IPAQ), 3-day food record, and visual appetite scale (VAS) questionnaires are completed for all individuals before and after the study. Anthropometric measurements and evaluation of leptin and ghrelin hormones 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.

Participants/Inclusion and exclusion criteria

Inclusion criteria: people 30 to 65 years old with metabolic syndrome (MS) Non-inclusion criteria: pregnancy; lactation; Kidney, liver, systemic, metabolic, endocrine, and cardiovascular diseases except diabetes, dyslipidemia, and hypertension; take any supplements or antibiotics during 3 previous months.

Intervention groups

Group 1 receives the 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

Primary outcomes: leptin hormone, ghrelin hormone, and appetite status Secondary outcomes: anthropometric factors

General information

Reason for update

Due to the lack of sufficient budgets, it was not possible to measure blood lipid indices after the study, and these indices were removed from the title. Also, due to the fact that most patients with metabolic syndrome were taking medication, we had difficulty finding patients and had to change the inclusion criteria. Finally, we included the patients who were receiving medicine in the study.

Acronym

IRCT registration information

IRCT registration number: **IRCT20220315054290N1**
Registration date: **2022-04-03, 1401/01/14**
Registration timing: **prospective**

Last update: **2023-08-08, 1402/05/17**
Update count: **1**

Registration date

2022-04-03, 1401/01/14

Registrant information

Name

Farzaneh Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-06-22, 1401/04/01
Expected recruitment end date
2022-10-22, 1401/07/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Production of Functional Oral Powder Enriched with Curcumin, Probiotics, and their Combination and Determination of their Effect on Appetite, Leptin, and Ghrelin Hormones and Some Anthropometric Indices in Patients with Metabolic Syndrome with Overweight or Obesity: a Randomized Double-Blind Controlled Clinical Trial

Public title
The Effect of Oral Powder Enriched with Curcumin and Probiotics on 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 Suffering from kidney, liver, and systemic diseases at the beginning of the study Metabolic, endocrine, and cardiovascular diseases except diabetes, dyslipidemia, and hypertension Take any supplements or antibiotics during the previous 3 months
Age
From **30 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

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.
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
2022-01-30, 1400/11/10
Ethics committee reference number
IR.SUMS.SCHEANUT.REC.1400.092

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
Leptin hormone
Timepoint

Before the study and 8 weeks after the start of the study

Method of measurement

Leptin kit (ELISA)

2

Description

Ghrelin hormone

Timepoint

Before the study and 8 weeks after the start of the study

Method of measurement

Ghrelin kit (ELISA)

3

Description

Appetite

Timepoint

Before the study and 8 weeks after the start of the study

Method of measurement

Visual Analog Scale (VAS) questionnaire

Secondary outcomes

1

Description

Weight

Timepoint

Before the intervention and 8 weeks after the start of the intervention

Method of measurement

Scale

2

Description

Waist circumference

Timepoint

Before the intervention and 8 weeks after the start of the intervention

Method of measurement

Inelastic tape

3

Description

Body fat percentage

Timepoint

Before the intervention and 8 weeks after the start of the intervention

Method of measurement

Body analyzer device

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

Namazi Square, Zand Ave

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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
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
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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