Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

The effect of synbiotic supplementation on anthropometric parameters, lipid profiles, total antioxidant capacity and malondialdehyde in patients with metabolic syndrome, an approach to prevent cardiovascular disease

Protocol summary

Study aim

Determination of the effects of synbiotic supplementation on anthropometric indices, body composition, lipid profile, total antioxidant capacity and malondialdehyde in patient with metabolic syndrome

Design

A randomized, placebo-controlled, double-blind parallel-group clinical trial. Fourty eight participants will be randomly allocated to two groups, one group receives synbiotic (n = 24) and another group receives placebo (n = 24).

Settings and conduct

individuals with metabolic syndrome will be recruited from Isfahan Endocrine & Metabolism Research Center (IEMRC), Isfahan, Iran.The synbiotic supplements and placebos will be packed in similar boxes, and the researcher and the patients will not be aware of the content of the pack until the end of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: willingness to participate; age of 20 to 55 years BMI > 25 kg/m2 waist circumference ≥88 cm in women and waist circumference ≥102 cm in men, serum triglyceride ≥150 mg/dl , serum HDL cholesterol <40 mg/dl in men and <50 mg/dl in women, fasting blood glucose ≥100 mg/dl Exclusion critaria: participating in weight loss or weight gain programs; history of mental disease , cancer,cardiovascular disease. Thyroid, pulmonary, renal and hepatic problems, eating disorders Pregnant, lactating and post menopausal women; Taking any dietary supplements, probiotic, prebiotic and synbiotic food products, antibiotics, drugs that affect appetite and body weight, and anti-inflammatory drugs; History of allergies to probiotics, prebiotics and maltodextrin products

Intervention groups

Individuals will be divided into two groups to receive two 500 mg synbiotic capsules or two 500 mg placebo capsules per day for 8 weeks.

Main outcome variables

Anthropometric indices; Body composition; Lipid profile; Total antioxidant capacity; Malondialdehyde

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140208016529N5**
Registration date: **2020-02-02, 1398/11/13**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-02, 1398/11/13**
Update count: **0**

Registration date

2020-02-02, 1398/11/13

Registrant information

Name

Mohammad hassan Entezari

Name of organization / entity

Isfahan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-14, 1398/09/23

Expected recruitment end date

2020-03-18, 1398/12/28

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of synbiotic supplementation on anthropometric parameters, lipid profiles, total antioxidant capacity and malondialdehyde in patients with metabolic syndrome, an approach to prevent cardiovascular disease

Public title
The effect of synbiotic supplementation in patients with metabolic syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria: Willingness to participate in projects Women and men aged 20-55 years Waist circumference ≥88 cm in women and waist circumference ≥102 cm in men, serum triglyceride ≥150 mg/dl, serum HDL cholesterol <40 mg/dl in men and <50 mg/dl in women, fasting blood glucose ≥100 mg/dl body mass index > 25 kg/m2
Exclusion criteria:
Mental illness, cancer, thyroid, cardiovascular, pulmonary, kidney, liver, eating disorders and digestive diseases Pregnancy or lactation or menopause Participate in weight loss or weight loss programs 3 months before the start of the study Use of Probiotic, Prebiotic and Synbiotic Foods, Antibiotic Antioxidants, Multivitamin, Nicotinic Acid and any dietary supplement 2 months before starting the study Drugs affecting appetite and body weight and anti-inflammatory drugs A history of allergies to pro-biotic, prebiotic and maltodextrin products
Age
From **20 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization with size 4
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is a randomized double-blind clinical trial. Participants and investigators will be blinded to the allocation of synbiotic or placebo.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ehtics committe of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences ,Hezarjerib St.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2019-06-26, 1398/04/05
Ethics committee reference number
IR.MUI.RESEARCH.REC.1398.188

Health conditions studied

1

Description of health condition studied
Metabolic syndrome
ICD-10 code
E88.9
ICD-10 code description
Metabolic disorder, unspecified

Primary outcomes

1

Description
Weight
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Scale-mounted stadiometer(Seca)

2

Description
Waist circumference
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement

Flexible tape

3

Description
High density lipoprotein (HDL)
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Colorimetric method

4

Description
Triglyceride
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Colorimetric method

5

Description
Body mass index (BMI)
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
BMI=weight(kg)/square of height(m)2

Secondary outcomes

1

Description
Hip circumference
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Flexible tape

2

Description
Malondialdehyde (MDA)
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Colorimetric method

3

Description
Total antioxidant capacity
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Colorimetric method

4

Description
Body fat Percent
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Body composition analyzer

5

Description
Waist circumference to Hip circumference ratio (WHR)
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
WHR=Waist circumference (cm)/Hip circumference (cm)

6

Description
Low density lipoprotein (LDL)
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Colorimetric method

7

Description
Energy content of food
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Food record questionnaire

8

Description
Physical activity energy expenditure
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Metabolic equivalent of tasks questionnaire

Intervention groups

1

Description
Intervention group: Synbiotic Supplement, as 500 mg capsule, twice a day orally, for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: Placebo (as 500 mg capsule, maltodexterin), quite similar to synbiotic capsules, twice a day orally, for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan Endocrine and Metabolism Research Center

Full name of responsible person
Mohammad Hasan Entezari

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Khorram street, Jomhouri Sq.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Shaghayegh Haghjoo

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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
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 Hasan Entezari

Position
Associate professor

Latest degree
Ph.D.

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)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
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
Starting 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
The data will provide for educational use.
From where data/document is obtainable
Dr Mohammad hasan Entezari entezari@hlth.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