# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

05 Jul 2026

## The effect of synbiotic supplementation on glycemic indices, inflammatory biomarkers, and appetite in patients with metabolic syndrome, an approach to prevent cardiovascular disease

## Protocol summary

**Study aim**

Determination of the effect of synbiotic supplementation on glycemic indices, inflammatory biomarkers (hs-CRP, TNFα) and appetite in patients 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**

Fasting blood sugar, fasting insulin,HOMA-IR, quantitative insulin sensitivity check index, High Sensitivity C-Reactive Protein, Tumor necrosis factor-α and appetite

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20140208016529N4**
Registration date: **2020-02-01, 1398/11/12**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-01, 1398/11/12**
Update count: **0**

**Registration date**

2020-02-01, 1398/11/12

**Registrant information**

**Name**
Mohammad hassan Entezari
**Name of organization / entity**
Isfahan university of medical sciences
**Country**
Iran (Islamic Republic of)
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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 glycemic indices, inflammatory biomarkers, and appetite in patients with metabolic syndrome, an approach to prevent cardiovascular disease

**Public title**
The effect of synbiotic supplementation on 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:**
History of mental disease, cancer, cardiovascular disease, thyroid, pulmonary,renal and hepatic problems and eating disorders Pregnant,lactating and post-menopausal women Participating in weight loss or weight gain programs three months before the intervention Taking any dietary supplements, probiotics, prebiotic, synbiotic food products, and antibiotics two months before the intervention Taking drugs that affect appetite and body weight,and anti-inflammatory drugs History of allergies to probiotics , prebiotics 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**
Ethics committee of Isfahan University of Medical Sciences
**Street address**
Isfahan University of Medical Sciences, Hezarjrib St.
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174673461
**Approval date**
2019-06-26, 1398/04/05
**Ethics committee reference number**
IR.MUI.RESEARCH.REC.1398.182

## 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**
Fasting Blood Sugar
**Timepoint**
Before intervention and 8 weeks after intervention
**Method of measurement**
Colorimetric method

### 2

**Description**
Serum insulin
**Timepoint**
Before intervention and 8 weeks after intervention
**Method of measurement**
ELISA

**3**

**Description**
Homeostasis model assessment of insulin resistance (HOMA-IR)
**Timepoint**
Before intervention and 8 weeks after intervention
**Method of measurement**
Equation

**4**

**Description**
Quantitative Insulin Sensitivity Check Index(QUICKI)
**Timepoint**
Before intervention and 8 weeks after intervention
**Method of measurement**
Equation

## Secondary outcomes

**1**

**Description**
High Sensitivity C-Reactive Protein
**Timepoint**
Before intervention and 8 weeks after intervention
**Method of measurement**
Biochemical method

**2**

**Description**
Tumor Necrosis Factor-Alpha (TNF-α)
**Timepoint**
Before intervention and 8 weeks after intervention
**Method of measurement**
ELISA

**3**

**Description**
Appetite
**Timepoint**
Before intervention and 8 weeks after intervention
**Method of measurement**
Visual Analogue Scale

**4**

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

**5**

**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 Endocrin and Metabolism Research Center
**Full name of responsible person**
Mohammad Hasan Entezari
**Street address**
Khorram St., 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
**Street address**
Isfahan University of Medical Sciences, Hezarjrib St.
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**Postal code**

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sh_haghjoo@med.mui.ac.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 Hasan Entezari

**Position**
Associate professor

**Latest degree**
Ph.D.

**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)**
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 Entezar ientezari@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**