

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effects of synbiotics supplement on anthropometric indices and body compositions in subjects aged 10-18 years with at least one item of metabolic syndrome

Protocol summary

Study aim

Determination and comparison of mean changes of anthropometric indices and body composition before and after the study between the placebo and synbiotic groups

Design

A double-blind randomized clinical trial with randomized block allocation of patients with volume 4 blocks divided into 35 groups of intervention and placebo.

Settings and conduct

Individuals 10-18 years old referred to Isfahan University of Medical Sciences, Primary Care Center for Prevention of Non-Communicable Diseases, are referred to the weight control clinic of Isfahan University of Medical Sciences. They will participate if they wish

Participants/Inclusion and exclusion criteria

Inclusion criteria are age 10 to 18 years and have at least one item of metabolic syndrome, not participating in weight loss programs for the past 6 months Exclusion Factors Unwillingness to Continue Attending Study, Tobacco Use, Chronic Disease Drug Use

Intervention groups

The group receiving two capsules of 0.5 g of synbiotic twice daily and Group receiving two 0.5 g placebo capsules 2 times a day

Main outcome variables

Weight BMI Waist circumference WHtR Hip circumference WHR Wrist circumference Neck circumference Fat mass The amount of protein The amount of minerals Whole body water Body muscle mass

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170501033747N2**

Registration date: **2019-11-28, 1398/09/07**

Registration timing: **prospective**

Last update: **2019-11-28, 1398/09/07**

Update count: **0**

Registration date

2019-11-28, 1398/09/07

Registrant information

Name

Motahar Heidari-Beni

Name of organization / entity

Isfahan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 3320

Email address

motahar.heidari@nutr.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of synbiotics supplement on anthropometric indices and body compositions in subjects aged 10-18 years with at least one item of metabolic syndrome

Public title

The effects of synbiotics supplement on item of metabolic syndrome

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range 10 to 18 years A parent's willingness to participate in the study and sign the informed consent form Has at least one item of metabolic syndrome Failure to participate in weight loss programs for the past 6 months

Exclusion criteria:

Unwillingness to continue attending the study Non-compliance with intervention (less than 90% product use) Major change in energy intake and nutrient intake or consumption of less than 800 kcal and more than 4200 kcal during the study based on the 3-day food registration method Start any weight loss or weight gain diet during the study Individual tobacco use during the study Use of antioxidants, multivitamins or any dietary supplements during intervention Antibiotic use during the study People with mental illnesses, cardiovascular, lung, liver, kidney, cancer, thyroid and eating disorders Type 1 diabetic patients with insulin and hypoglycemic drugs People taking drugs that affect appetite, body weight, blood sugar, lipid profile or anti-inflammatory drugs

Age

From **10 years** old to **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

During Random Allocation, patients are divided into two groups of placebo and placebo with permutation block method with volume 4 blocks. In the permutation block procedure with blocks of volume 4, six blocks are formed, each block containing an equal number of intervention or placebo subjects. These groups include the blocks "ABAB", "BABA", "AABB", "BBAA", "ABBA" and "BAAB". The blocks are then randomly arranged and numbered with the help of a statistics consultant. Then, participants receive the intervention or placebo according to this arrangement, and this cycle is repeated until the end of the sampling.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind randomized clinical trial, in which the participants and the investigator do not know which supplement is placebo and which is synbiotic.

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

Hezarjrib street, Isfahan University of Medical Sciences, Research Institute for Primordial Prevention of Non-communicable Disease, Child Growth and Development Research Center

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2019-11-13, 1398/08/22

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.449

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**

Changes in anthropometric indices and body composition

Timepoint

The beginning and the end of the study

Method of measurement

body composition analysis

Secondary outcomes**1****Description**

"Abdominal Volume Index" and "Conicity Index" and "A Body Shape Index"

Timepoint

The beginning and the end of the study

Method of measurement

equation

Intervention groups**1****Description**

Intervention group: Two 0.5 g capsules of synbiotic twice daily for 8 weeks

Category

Prevention

2**Description**

Control group: Two 0.5 g placebo capsules (maltodextrin) 2 times daily for 8 weeks

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Research Institute for Primordial Prevention of Non-communicable Disease

Full name of responsible person

Motahar Heidari-Beni

Street address

Hezarjrib street, Isfahan University of Medical Sciences, Research Institute for Primordial Prevention of Non-communicable Disease, Child Growth and Development Research Center

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 5284

Email

heidari.motahar@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Mrs Afshari

Street address

Hezarjrib street, Isfahan University of Medical

Sciences, Research Institute for Primordial Prevention of Non-communicable Disease, Child Growth and Development Research Center

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 3078

Email

heidari.motahar@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Non

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

Motahar Heidari-Beni

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Phone

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Email

heidari.motahar@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Motahar Heidari-Beni

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Province

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Postal code

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Phone

+98 31 3792 5284

Email

heidari.motahar@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Motahar Heidari-Beni

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Hezarjrib street, Isfahan University of Medical Sciences, Research Institute for Primordial Prevention

of Non-communicable Disease, Child Growth and Development Research Center

City

isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 5284

Email

heidari.motahar@gmail.com

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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All potential data can be shared after unidentifiable people

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Any analysis on the data is possible

From where data/document is obtainable

heidari.motahar@gmail.com

What processes are involved for a request to access data/document

The applicant must email heidari.motahar@gmail.com. It should clearly explain where the data will be used

Comments