Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Iran (Islamic Republic of)

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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
Isfehan
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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mrs Afshari

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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

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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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Assistant Professor

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Other areas of specialty/work
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Other areas of specialty/work
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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
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