Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

The effect of synbiotic supplementation on lipid profile and inflammatory factors in subjects aged 8-18 years with at least one item of metabolic syndrome, an approach to prevent cardiovascular disease.

Protocol summary

Study aim
Determination and comparison of mean changes of glucose, fat and inflammatory factors 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 8-18 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: age 10 to 18 years; have at least one metabolic syndrome criteria; not participating in weight loss programs for the past 6 months. Exclusion criteria: unwillingness to participate in the study; tobacco use; chronic diseases, drug use.

Intervention groups
Intervention group receiving two capsules of 0.5 g of synbiotic twice daily and the control group receiving two 0.5 g placebo capsules 2 times a day.

Main outcome variables
Fasting Blood Sugar (FBS); Blood Triglycerides (TG); Total Blood Cholesterol (TC); High-Density Lipoprotein (HDL); Low-Density Lipoprotein (LDL); Tumor Necrosis Factor-Alpha (TNF-Alpha); and High-Sensitivity C-Reactive Protein (HS-CRP).

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140208016529N7**
Registration date: **2021-07-18, 1400/04/27**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-18, 1400/04/27**
Update count: **0**

Registration date
2021-07-18, 1400/04/27

Registrant information

Name
Mohammad hassan Entezari

Name of organization / entity
Isfahan university of medical sciences

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Iran (Islamic Republic of)

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+98 31 3668 8487

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-14, 1400/04/23

Expected recruitment end date
2021-10-15, 1400/07/23

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of synbiotic supplementation on lipid profile and inflammatory factors in subjects aged 8-18 years with at least one item of metabolic syndrome, an

approach to prevent cardiovascular disease.

Public title
The effect of synbiotic supplementation on metabolic syndrome items in subjects aged 8-18 years
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 **8 years** old to **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- 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
2019-07-28, 1398/05/06
Ethics committee reference number
IR.MUI.RESEARCH.REC.1398.184

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 Glucose (GBG)
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Colorimetric method

2

Description
High Sensitivity C-Reactive Protein (hs-CRP)

Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Biochemical method

3

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

4

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

5

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

6

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

7

Description
Total Cholesterol (TC)
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Colorimetric method

Secondary outcomes

1

Description
The amount of energy consumed by food
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Food record questionnaire

2

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: Intervention group: Two 0.5 g capsules of synbiotic twice daily for 8 weeks
Category
Treatment - Drugs

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
Mohammad Hasan Entezari
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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
Shaghayegh Haghjoi Javanmard

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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
Isfahan 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
PhD of nutrition, Assistant 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
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

Dr. Mohammad hasan Entezari entezari@hlth.mui.ac.ir

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

The applicant must email entezari@hlth.mui.ac.ir. It should clearly explain where the data will be used

Comments