Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Assessment of the effects of Probiotic supplementation on body mass index in overweight and obese adults

Protocol summary

Study aim
Determining of the effects of probiotic supplementation on body mass index in overweight and obese adults

Design
This is a randomized, controlled double-blind, clinical trial with parallel-group which will be conducted on 74 people with overweghit and obese. Participants are randomly assigned to tow intervention and control groups and each participant is assigned a code.

Settings and conduct
74 patient with overweight and obese among people of eligible and referred to private Clinic , Rasht, Iran in the study will be selected. In this study, patient will be randomly divided into two groups, each will be received supplement or placebo for 12 weeks.37 of patients will be consume 500 mg probiotic and 37 of patients will be consume 500 mg placebo capsules daily. Before the study, containers will be coded as A and B by a person other than the study researchers . Physical activity information will be collected using short-IPAQ (International Physical Activity Questionnaire) and demographic information through a general information questionnaire. In order to evaluate dietary intake of patients , 24-hr recalls will be completed by interviewing the patient for 3 days (two normal days and a weekend day). Anthropometric indicators will also be measured. All these steps will be completed at the start and end of the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Willingness to cooperate, Body mass index more than 25 kg/m2, Age range from 18 to 60 years, exclusion criteria: Having acute or chronic metabolic disease, pregnancy and breastfeeding and Menopause.

Intervention groups
Individuals will randomly divided into two groups to receive 500 mg probiotic supplementation or placebo per day for 12 weeks.

Main outcome variables
Body mass index, Weight, Waist circumference, Hip circumference, Waist–Hip Ratio, Body fat

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220425054653N1**
Registration date: **2022-09-11, 1401/06/20**
Registration timing: **prospective**

Last update: **2022-09-11, 1401/06/20**
Update count: **0**

Registration date
2022-09-11, 1401/06/20

Registrant information

Name
Maryam Izanlou

Name of organization / entity
The Islamic Azad University, Science and Research Branch, Tehran

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-13, 1401/06/22

Expected recruitment end date
2022-11-06, 1401/08/15

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessment of the effects of Probiotic supplementation on body mass index in overweight and obese adults

Public title
The effect of probiotic supplementation on obesity
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age range from 18 to 60 years Body mass index more than 25 kg/m2 full person's willingness to cooperate in the project
Exclusion criteria:
Having an acute or chronic metabolic disorder Pregnancy, lactation, Menopause Having a Weight loss diet in the last two months Intake of antibiotic
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
It will be done with simple random method using the lottery. For each patient, a number or code is provided, then the numbers will be written on pieces of paper. The pieces of paper are placed in a container and well stirred, and the sample is selected according to the sample size.
Blinding (investigator's opinion)
Double blinded
Blinding description
Prior to the beginning of the study, the canisters containing the capsules are coded by individuals other than the research team, A and B, so that the knowledge of the type of capsules received by each group is not known to the researcher. Since this study is double blind, the subjects , the researchers have no information about the individuals located in the studied and control groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Islamic Azad University-Science and Research Branch
Street address
End of Shahid Sattari Highway - University Square - Shahadai Hesarak Boulevard - Islamic Azad University Science and Research Branch
City
Tehran
Province
Tehran
Postal code
۱۴۷۷۸۹۳۸۵۵
Approval date
2022-08-21, 1401/05/30
Ethics committee reference number
IR.IAU.SRB.REC.1401.134

Health conditions studied

1

Description of health condition studied
Overweight and Obesity
ICD-10 code
E66
ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description
Body Mass Index
Timepoint
Before the start of the intervention and after the end of the intervention
Method of measurement
Calculated (Divide the weight in kilograms by the square of the height in meters)

2

Description
Weight
Timepoint
Before the start of the intervention and after the end of the intervention
Method of measurement
Weight of the participants with minimal clothing and without shoes using a Seca scale

3

Description
Waist circumference

Timepoint
Before the start of the intervention and after the end of the intervention
Method of measurement
Tape measure

4

Description
Hip circumference
Timepoint
Before the start of the intervention and after the end of the intervention
Method of measurement
Tape measure

5

Description
Waist to hip ratio
Timepoint
Before the start of the intervention and after the end of the intervention
Method of measurement
Calculate waist circumference divided by hip circumference

6

Description
Body fat
Timepoint
Before the start of the intervention and after the end of the intervention
Method of measurement
Using the Deurenberg equation

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Daily intake of a probiotic capsule containing (Lactobacillus rhamnosus, Lactobacillus casei, Lactobacillus acidophilus, Lactobacillus plantarum, Bifidobacterium lactis, Bifidobacterium brouh, Bifidobacterium longum, Bifidobacterium bifidum, Streptococcus thermophilus,10^9 cfu), for 12 week, Production company: Danesh Bonyan Zist Takhmir
Category
Treatment - Drugs

2

Description
Control group: A daily placebo capsule with appearance characteristics including shape, color, smell, and taste completely similar to a probiotic capsule without microorganisms, for 12 weeks, Production company: Danesh Bonyan Zist Takhmir
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic
Full name of responsible person
Maryam Izanlou
Street address
Golsar Crossroad, next to Dr. Behermand Pharmacy, Aban Medical Complex
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
DR jazayery
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End of Shahid Sattari Highway - University Square - Shahadai Hesarak Boulevard - Islamic Azad University Science and Research Branch
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Phone
+98 21 4486 1815
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med@srbiau.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
danesh bonyan zist tahkmir
Proportion provided by this source
70
Public or private sector
Private
Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Abolghassem Jazayery

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Position

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Latest degree

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Other areas of specialty/work

Nutrition

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Person responsible for updating data

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student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to ethical issues

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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