Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of synbiotic supplementation on anthropometric indices and appetite level in obese women under weight loss diet

Protocol summary

Study aim

Determining the effect of synbiotic supplementation on anthropometric indicators and appetite level in obese women under weight loss diet

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 66 patients. A research assistant not involved in the study will perform the randomization sequence, enroll participants, and assign them to interventions.

Settings and conduct

First, during a briefing session, the study method and objectives will be explained to obese women referring to Shahr Abadan nutrition and diet therapy clinic. Then, written consent will be obtained from the people who want to participate in the study and the criteria for entering the study. Next, we will block people according to BMI. First, we will divide people into two blocks according to BMI. A research assistant not involved in the study will perform the randomization sequence, enroll participants, and assign them to interventions. Researchers and participants will be blinded to treatment groups until the final analysis. Both synbiotic and placebo capsules will be packaged by the supplier.

Participants/Inclusion and exclusion criteria

BMI between 30 and 39.99 kg/m2 Being in the age range of 30 to 50 years

Intervention groups

In this group, people will receive synbiotic supplements for 12 weeks.

Main outcome variables

Weight، Body Mass Index، Waist Circumference، Hip Circumference، Ratio of Waist to Hip Circumference، Fat Mass، Appetite، Fat Free Mass، A Body Shape Index، Body Fat Index، Abdominal Volume Index، Conicity Index، Weight adjusted Waist IndeX، Waist to Height Ratio، body roundness index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231113060047N1**
Registration date: **2023-12-05, 1402/09/14**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-05, 1402/09/14**
Update count: **0**

Registration date

2023-12-05, 1402/09/14

Registrant information

Name
Fateme Pakbaz
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of synbiotic supplementation on anthropometric indices and appetite level in obese women under weight loss diet

Public title

The effect of synbiotic supplementation on anthropometric indices and appetite level in obese women under weight loss diet

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Body mass index between 30 and 39.99 kg/m2 Willingness to cooperate Female gender Stable weight in the last three months Being in the age range of 30 to 50 years

Exclusion criteria:

Pregnancy, breastfeeding and menopause Use of any type of antibiotic in the last 3 weeks Use of weight loss and appetite suppressants Suffering from cancer, cardiovascular disease, diabetes, acute gastrointestinal diseases, infectious diseases, chronic kidney and liver diseases except non-alcoholic fatty liver disease Using any type of food supplement and probiotic products Unwillingness to continue cooperation Death Failure to comply with the intervention (use of less than 90% of supplements) Allergic reaction to Yari supplement

Age

From **30 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the participants are classified into grade A obesity (34.9-30) and grade 2 obesity (34.9-39.9) by stratified blocked randomization method and based on body mass index. One of the groups receiving the probiotic supplement or the placebo group is assigned. To randomly assign people to two groups, Stratified Blocked Randomization is used and randomization is done separately within each group. The size of the blocks is in the form of 4, where two allocations to the intervention group (A) and two allocations to the placebo group (B) are considered. that 6 different permutations AABB, ABAB, BBAA, BABA, ABBA, and BAAB will be created.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be double-blind, so the researcher and the participants will not know which group they belong to. For blinding, intervention and placebo capsules are presented in similar shapes, colors, and sizes. These capsules are coded by someone other than researchers and then the capsules are given to the participants. Until the end of the study and after analyzing the data, the researchers will not know about the intervention and control groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Jundishapur Ahvaz University, Ahvaz, Iran

Street address

132 / 5,000 Translation results Translation result Academic City - Ahvaz University of Medical Sciences and Health Services - Research and Technology Development Deputy Building - Nutrition and Metabolic Diseases Research Center

City

AHVAZ

Province

Khouzestan

Postal code

6135715794

Approval date

2023-11-06, 1402/08/15

Ethics committee reference number

IR.AJUMS.REC.1402.411

Health conditions studied

1

Description of health condition studied

obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

Body Mass Index

Timepoint

The beginning of the intervention, week 6 and week 12

Method of measurement

Height with the help of a calibrated meter with an accuracy of 0.5 cm, which is connected to the wall at a

distance of one meter from the ground level, in such a way that the person is completely attached to the wall from the back, both feet are placed together, and the head is along the ground level and looking The person will be measured straight ahead. People's weight will be measured with the help of a Seka digital scale with an accuracy of 0.5 kg with the lightest clothes and bare feet. The body mass index will also be obtained with the help of placing the value of height and weight in the formula.

Secondary outcomes

1

Description
waist circumference
Timepoint
The beginning of the intervention, week 6 and week 12
Method of measurement
The circumference of the waist will be measured with the help of a graduated meter with a measurement accuracy of 0.5 cm.

2

Description
Hip Circumference
Timepoint
The beginning of the intervention, week 6 and week 12
Method of measurement
Hip circumference will be measured with the help of a graduated meter with a measurement accuracy of 0.5 cm.

3

Description
Waist-Hip Ratio
Timepoint
The beginning of the intervention, week 6 and week 12
Method of measurement
Waist circumference divided by hip circumference

4

Description
Fat Mass
Timepoint
The beginning of the intervention, week 6 and week 12
Method of measurement
Body fat will be measured by bioelectrical impedance analysis using inbody x-contact 356 made in South Korea.

5

Description
Appetite
Timepoint
The beginning of the intervention, week 6 and week 12
Method of measurement
In order to check the state of appetite, the subjects will be asked to indicate the level of appetite, satisfaction and willingness to eat by marking a position along a continuous line between 0 and 100 mm.

6

Description
Fat Free Mass
Timepoint
The beginning of the intervention, week 6 and week 12
Method of measurement
Fat free mass will be measured by bioelectrical impedance analysis using inbody x-contact 356 made in South Korea.

7

Description
A Body Shape Index
Timepoint
The beginning of the intervention, week 6 and week 12
Method of measurement
Body shape index is calculated through waist circumference, height and body mass.

8

Description
Body Adiposity Index
Timepoint
The beginning of the intervention, week 6 and week 12
Method of measurement
An index to estimate body fat, which is calculated using hip circumference and height.

9

Description
Abdominal Volume Index
Timepoint
The beginning of the intervention, week 6 and week 12
Method of measurement
An index to estimate abdominal fat, which is used to calculate waist circumference and hip circumference.

10

Description
Conicity Index
Timepoint
The beginning of the intervention, week 6 and week 12
Method of measurement
An index measuring central obesity, which is used to calculate waist circumference, height, and weight.

11

Description
Weight-adjusted-Waist Index
Timepoint
The beginning of the intervention, week 6 and week 12
Method of measurement
An innovative measure to measure obesity is the result

of dividing the waist circumference by the square root of weight.

12

Description
Waist to Height Ratio
Timepoint
The beginning of the intervention, week 6 and week 12
Method of measurement
Waist size divided by height

13

Description
Body Roudness Index
Timepoint
The beginning of the intervention, week 6 and week 12
Method of measurement
An index to predict body fat and the percentage of visceral fat tissue, which is used to calculate it from height and waist circumference.

14

Description
Diet intake (energy, carbohydrates, fat, protein)
Timepoint
The beginning of the intervention, week 6 and week 12
Method of measurement
Using Nutritionist IV software

15

Description
physical activity
Timepoint
The beginning of the intervention, week 6 and week 12
Method of measurement
International Physical Activity Questionnaire

Intervention groups

1

Description
Intervention group: In this group of people, for 12 weeks, 2 capsules of Synbiotic Femilact Bio Fermentation Co., which contains Lactobacillus rhamnosus, Bifidobacterium lactis, Lactobacillus casei, Bifidobacterium Brue, Lactobacillus acidophilus, Bifidobacterium longum, Lactobacillus plantarum, Bifidobacterium bifidum and Streptococcus thermophilus (CFU blend 109)) will receive.
Category
Treatment - Drugs

2

Description
Control group: Control group: In this group, people will receive a placebo (containing lactose monohydrate, talc, magnesium stearate, maltodextrin, silicon dioxide, microcrystalline cellulose, sodium starch glycolate) for 12 weeks, which looks like a synbiotic supplement.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Abadan University of Medical Sciences
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Jundishapur University of Medical Sciences, Ahvaz
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
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Fateme Pakbaz
Position
Masters student
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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
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
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The effect of synbiotic supplementation on anthropometric indices and appetite level in obese women under weight loss diet
When the data will become available and for how long
After the publication of the article
To whom data/document is available
all people
Under which criteria data/document could be used
study
From where data/document is obtainable
Dr Ahmad Zare Javid
What processes are involved for a request to access data/document
send mail

Comments