Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of supplementation with Lactobacillus rhamnosus, Lactobacillus fermentum, and Lactobacillus plantarum on anthropometric indices, appetite, and serum level of Nesfatin, Omentin-1, LPS, liver function markers, metabolic parameters, oxidative stress, and inflammatory biomarkers in obese individuals: a triple blinded RCT

Protocol summary

Study aim

The assessment of the effect of supplementation with Lactobacillus rhamnosus, Lactobacillus fermentum, and Lactobacillus plantarum on anthropometric indices, appetite, and serum level of Nesfatin, Omentin-1, LPS, liver function markers, metabolic parameters, oxidative stress, and inflammatory biomarkers in obese individuals

Design

A clinical trial with control group and four parallel groups of 25 obese people, randomized and triple blinded

Settings and conduct

Those who refer to Fardis Karaj laboratory are invited to participate in this study if they have the conditions to participate in the study and are willing to cooperate. People who signed the informed consent were randomly divided into the four mentioned groups. The supplements are prepared in the form of 1 gram powder sachets with similar packaging (for blinding) and with codes A to D, and people are requested to take 1 gram sachet daily before meals (mixed with water) for 2 Consume moon. At the beginning and end of the intervention, fasting blood sampling is done to determine the serum levels of the following biochemical variables in the amount of 6 cc.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Volunteer Obese people in the range of body mass index(30≤BMI ≤ 40) aged 18-60 years. Exclusion criteria: Allergy to probiotics; Having Diabetes, kidney disease, liver disease, and Thyroid disorders; Having a special diet to treat obesity in the last three months; Taking corticosteroids and/ or antibiotics; Regular Consumption of probiotics and/or nutritional supplements; Gastric surgery; pregnancy or lactation; Smoking and or drinking alcohol.

Intervention groups

Group1:Probiotic supplementation containing Lactobacillus fermentum (NCBI MT registration code 994667) Group2: Probiotic supplementation containing Lactobacillus rhamnosus (NCBI MT registration code 995144) Group3: Probiotic supplementation containing Lactobacillus plantarum (NCBI MT 012188) Control group: Placebo as pure maltodextrin

Main outcome variables

Changes of anthropometric measurements, appetite, serum levels of nesfatin, omentin, Lipopolysaccharide (LPS,) metabolic markers, oxidative stress, and inflammatory marker

General information

Reason for update

Addition of some new parameters to the present project

Acronym

IRCT registration information

IRCT registration number: **IRCT20220608055106N1**
Registration date: **2022-07-03, 1401/04/12**
Registration timing: **prospective**

Last update: **2024-08-21, 1403/05/31**
Update count: **1**

Registration date

2022-07-03, 1401/04/12

Registrant information

Name

Jamileh Ghalami

Name of organization / entity

The university of Alborz

Country

Iran (Islamic Republic of)

Phone

+98 26 3664 8761

Email address

s_ghalami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2023-08-01, 1402/05/10

Actual recruitment start date

2022-10-23, 1401/08/01

Actual recruitment end date

2023-11-26, 1402/09/05

Trial completion date

empty

Scientific title

The effect of supplementation with Lactobacillus rhamnosus, Lactobacillus fermentum, and Lactobacillus plantarum on anthropometric indices, appetite, and serum level of Nesfatin, Omentin-1, LPS, liver function markers, metabolic parameters, oxidative stress, and inflammatory biomarkers in obese individuals: a triple blinded RCT

Public title

Effect of probiotics supplementation in the control of obesity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Obese people in the range of body mass index(30≤BMI ≤ 40) Age group of 18-60 years Volunteers

Exclusion criteria:

Allergy to probiotics Having Diabetes, kidney disease, liver disease, Thyroid disorders Having a special diet to treat obesity in the last three months Taking corticosteroids and/ or antibiotics Regular Consumption of probiotics and/or nutritional supplements Gastric surgery Pregnancy. lactation Smoking and or drinking alcohol

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **100**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method with non-matched block size will be studied. For this purpose, a list of the order of allocation of samples by the second (non-original) researcher and using the software provided on the website https://www.sealedenvelope.com. Prepared and the size of the blocks will be two, four and six.

Blinding (investigator's opinion)

Triple blinded

Blinding description

After randomization, intervention groups 1 to 3 received powdered sachets containing isolated probiotics Lactobacillus rhamnus, fermentum, and plantarum, respectively, and group 4 received sachets containing maltodextrin as 1 sachet daily before the meal for 60 days. Sachets related to each group were prepared in similar and same-colored packages and provided to them monthly. For further blinding, the packaging of supplements and their coding (A-D) were done by someone outside of the project and other than the main researchers. The patient, doctors, statistical analyst, and the main researcher did not know those codes. After completing the study, the codes will be decoded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University of Medical Sciences

Street address

Ethics committee unit,Vice Chancellor for Research, No.20, Saffarian alley, 45 Metri Golshahr street

City

Karaj

Province

Alborz

Postal code

3149779453

Approval date

2022-05-21, 1401/02/31

Ethics committee reference number

IR.ABZUMS.REC.1401.054

2

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address
Golgasht, Tabriz University of Medical Sciences
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Postal code
5166614711
Approval date
2024-07-08, 1403/04/18
Ethics committee reference number
IR.TBZMED.REC.1403.264

3

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2024-08-05, 1403/05/15
Ethics committee reference number
IR.TBZMED.REC.1403.361

4

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Approval date
2024-08-05, 1403/05/15
Ethics committee reference number
IR.TBZMED.REC.1403.362

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
Anthropometric indicators (height, weight, BMI, waist circumference)
Timepoint
At first and end of two months intervention
Method of measurement
Weight scale, Meter

2

Description
Novel anthropometric indexes e.g., ABSI, BRI)
Timepoint
Weight scale, Meter
Method of measurement
Weight scale, Meter, related formula

3

Description
appetite
Timepoint
At first and end of two months intervention
Method of measurement
questionnaire

4

Description
Serum level of Nesfatin
Timepoint
At first and end of two months intervention
Method of measurement
Elisa kit

5

Description
serum level of Omentin-1
Timepoint
At first and end of two months intervention
Method of measurement
Elisa kit

6

Description
serum level of LPS
Timepoint
At first and end of two months intervention
Method of measurement
Elisa kit

7

Description
Liver function test (ALT, AST, ALP)
Timepoint
At first and end of two months intervention

Method of measurement
Auto-analyzer based on the principle of photometry

8

Description
FBS
Timepoint
At first and end of two months intervention
Method of measurement
Auto-analyzer based on the principle of photometry

9

Description
serum Insulin
Timepoint
At first and end of two months intervention
Method of measurement
Elisa kit

10

Description
lipid profile (TC, TG, LDL.C, HDL.C)
Timepoint
At first and end of two months intervention
Method of measurement
Auto-analyzer based on the principle of photometry

11

Description
MDA
Timepoint
At first and end of two months intervention
Method of measurement
Spectrophotometer

12

Description
TAC
Timepoint
At first and end of two months intervention
Method of measurement
Elisa kit

13

Description
TOC
Timepoint
At first and end of two months intervention
Method of measurement
Elisa kit

14

Description
CRP
Timepoint
At first and end of two months intervention
Method of measurement
photometry

15

Description
IL-6
Timepoint
At first and end of two months intervention
Method of measurement
ELISA KIT

16

Description
IL-1 B
Timepoint
At first and end of two months intervention
Method of measurement
ELISA KIT

17

Description
TNF alfa
Timepoint
At first and end of two months intervention
Method of measurement
ELISA KIT

Secondary outcomes

1

Description
Blood urea nitrogen
Timepoint
At first and end of two months intervention
Method of measurement
autoanalyzer

2

Description
CREATININ
Timepoint
At first and end of two months intervention
Method of measurement
autoanalyzer

Intervention groups

1

Description
Intervention group: (group1) Probiotic supplement in powder sacs containing Lactobacillus fermentum 014 NIMBB (NCBI MT registration code 994667) isolated from the ridge (for 60 days)
Category
Treatment - Drugs

2

Description
Intervention group:(Group2) Lactobacillus rhamnosus NIMBB006 (NCBI MT registration code 995144) isolated from breast milk at a rate of 2 * 10 cfu (for 60 days)
Category
Treatment - Drugs

3

Description
Intervention group (Group3) Lactobacillus plantarum isolated from camel milk (cfu 9 10 * 2 NCBI MT 012188)(for 60 days)
Category
Treatment - Drugs

4

Description
Control group: Placebo with tasteless maltodextrin 100 for 60 days(for 60 days)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Fardis laboratory
Full name of responsible person
Jamileh Ghalami
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No. 15 street, Fardis, Karaj
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Karaj University of Medical Sciences
Proportion provided by this source
30
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

2

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Parviz Shahabi
Street address
Vice Chancellor of Research of Tabriz University of Medical Sciences, University Street
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences
Proportion provided by this source
70
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
Karaj University of Medical Sciences
Full name of responsible person
Jamileh Ghalami
Position
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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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
results publication
When the data will become available and for how long
After publishing the articles
To whom data/document is available
Researchers
Under which criteria data/document could be used
with permission of the responsible members of the project
From where data/document is obtainable
Dr. Vahideh Ebrahimzadeh Attari, Faculty of Nutrition and Food Sciences, Tabriz University of Medical Sciences, ebrahimzadeh.va@gmail.com
What processes are involved for a request to access data/document
please send an Email to: ebrahimzadeh.va@gmail.com
Comments