

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Effects of probiotic yogurt containing *Lactobacillus acidophilus* La5, *Bifidobacterium* bb12, and *Lactobacillus casei* DN001 on serum Omentin ,Nesfatin-1and Adropin in Obese and Overweight people with Low Calorie Diet

Protocol summary

Summary

Objective: The main objective of this study is to assess the effects of some probiotics on changes in some adipokines secreted by adipose tissue to reduce inflammation in the body in an overweight and obese adult population. Design of study: Randomized, double blind, placebo controlled, single center and phase 2-3 trial. Setting and conduct: 60 overweight or obese volunteer age between 20 -50 years old and BMI between 25 – 35 kg/m2 will be recruited. We have 2 groups: 30 persons that will eat probiotic yogurt with L.casei DN01 - lactobacillus acidofillus La5- Bifidobacter bb12. With weight reduction diet, 30 persons that will eat regular yogurt with weight reduction diet. The duration of intervention is 8 weeks. Main outcome measures: Nesfatin-1, Adropin and Omentin will measure with ELIZA . With BIA method we will measure the fat percent of the body of participants (after and before of study).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201509292709N34**

Registration date: **2015-10-22, 1394/07/30**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-10-22, 1394/07/30

Registrant information

Name

Farzad Shidfar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8862 2755

Email address

shidfar.f@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-05-20, 1395/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of probiotic yogurt containing *Lactobacillus acidophilus* La5, *Bifidobacterium* bb12, and *Lactobacillus casei* DN001 on serum Omentin ,Nesfatin-1and Adropin in Obese and Overweight people with Low Calorie Diet

Public title

Effects of probiotic on secreted hormones by adipose tissue in overweight and obese people

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age of 20-50;BMI= 25-35; interesting in participation in research; without any metabolic disease,

CHD, diabetes, without autoimmune disease, cancer; without infection disease in research; without allergy for cow s milk; no smoking; no alcoholism; without any diet 2 mounts before research; no consumption food supplementation during research exclusion criteria: metabolic disease, CHD, diabetes, cancer; infection disease in research; allergy for cow s milk; smoking; alcoholism; diet 2 mounts before research; lactose deficiency; food supplementation during research; no interesting for participation

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

Not

Secondary trial Id

Not

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Faculty of Nutrition, School of Public Health, Iran University of Medical Sciences, next to the Milad hospital, the intersection of Sheikh Fazlallah and Shahid Chamran, Shahid Hemmat expressway

City

Tehran

Postal code

Approval date

2015-09-22, 1394/06/31

Ethics committee reference number

IR.IUMS.REC.1394.26381

Health conditions studied

1

Description of health condition studied

Overweight and Obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

fat percent

Timepoint

bigining of the study and ending of 12 weeks

Method of measurement

BIA method

2

Description

BMI

Timepoint

bigining of the study and ending of 12 weeks

Method of measurement

Formula

3

Description

Omentin ,Nesfatin-1 , Adropin

Timepoint

bigining of the study and ending of 12 weeks

Method of measurement

ELIZA

Secondary outcomes

empty

Intervention groups

1

Description

Itrvention group: 30 overwieght and obese persons with weight reduction and cunsumption of probiotic yogurt with lactobacilus acidophillus La5 and lactobacilus casei DN001 and bifidobacter bb12

Category

Placebo

2

Description

control group: 30 overwieght and obese persons with

weight reduction and consumption of regular yogurt with lactobacillus bulgaricus and Streptococcus thermophilus

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Azad university clinic of weight management

Full name of responsible person

Mitra Zarrati

Street address

unit4, First floor, Irane ma Building, No.1, Twenty-fourth Street, Farahani Street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. seyed Ali Javad Mousavi . Vice chancellor for research, Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, next to the Milad hospital, the intersection of Sheikh Fazlallah and Shahid Chamran, Shahid Hemmat expressway

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School of Public Health, Iran University of Medical Sciences

Full name of responsible person

Dr. Farzad Shidfar

Position

professor

Other areas of specialty/work

Street address

Faculty of Nutrition, School of Public Health, Iran University of Medical Sciences, next to the Milad hospital, the intersection of Sheikh Fazlallah and Shahid Chamran, Shahid Hemmat expressway

City

Tehran

Postal code

Phone

+98 21 8670 4711

Fax

Email

shidfar.f@iums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr.Mitra Zarrati

Position

Assistant Professor

Other areas of specialty/work

Street address

Faculty of Nutrition, School of Public Health, Iran University of Medical Sciences, next to the Milad hospital, the intersection of Sheikh Fazlallah and Shahid Chamran, Shahid Hemmat expressway

City

Tehran

Postal code

Phone

+98 21 8670 4814

Fax

Email

zarrati.m@iums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr.Mitra Zarrati

Position

Assistant Professor

Other areas of specialty/work

Street address

Faculty of Nutrition, School of Public Health, Iran University of Medical Sciences, next to the Milad hospital, the intersection of Sheikh Fazlallah and Shahid Chamran, Shahid Hemmat expressway

City

Tehran

Postal code

Phone

+98 21 8670 4814

Fax

Email

zarrati.m@iums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty