

# 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

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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**

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**Full name of responsible person**

Dr.Mitra Zarrati

**Position**

Assistant Professor

**Other areas of specialty/work**

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**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*