

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of daily consumption of probiotic versus low fat conventional yoghurt on weight loss in healthy obese women on an energy restricted diet (Novin Diet Protocol): a randomized controlled trial

#### Protocol summary

##### Summary

Probiotics are useful for controlling weight gain, preventing obesity, reducing fat deposition, improving energy metabolism, enhancing insulin sensitivity, treating obesity and treating insulin insensitivity. The purpose of this study is to compare the effects of the traditional low fat probiotic yogurt (containing of Lactobacillus acidophilus and bifidobacters) versus low fat yogurt on body weight, abdominal adiposity and other body measures in obese adults that receiving a low calorie diet, according to the protocol of Novin diet Clinic. 80 healthy subjects with BMI 25-45 kg/m<sup>2</sup> and waist circumference > 88 cm, non smoking, no-menopause, good general health, normal lipid level (healthy obese), no-diabetes were participated. Participants that intake antibiotic or any drugs with purpose decrease blood glucose or blood pressure or with abnormal thyroids hormones or become peregnant Will be excluded. Participants received diet according to Novin diet Clinic program for weight loss. Before the inclusion, patients were answered about amount and type of yogurt consumption. A 2 weeks probiotic dairy products washout period prior to intervention initiation was used. People who consumed 200-400 gram yogurt per day allowed to participate to the study. We randomly assigned participants to consume 400 g per day of conventional (n=40) or the probiotic group (n=40) for 12 weeks. Compliance was assessed by 3 days food record in the initiation, medium and end of study. Body weight is the main outcome of the study.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201402177754N8**  
Registration date: **2014-03-11, 1392/12/20**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2014-03-11, 1392/12/20

##### Registrant information

###### Name

Leila Shafiei Neek

###### Name of organization / entity

Faculty of Physical Education and Sport Sciences,  
University of Tehran

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2258 9952

###### Email address

shafieineek@ut.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Novin Diet Center

##### Expected recruitment start date

2014-04-21, 1393/02/01

##### Expected recruitment end date

2014-07-23, 1393/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of daily consumption of probiotic versus low fat conventional yoghurt on weight loss in healthy obese

women on an energy restricted diet (Novin Diet Protocol): a randomized controlled trial

#### Public title

Probiotic yogurt consumption on weight loss

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria:Willingness to enrollment to the study;Waist circumference > 88 cm;Non smoking; No-menopause;BMI: 25-45 kg/m2;Good general health;Normal lipid level (healthy obese);No-diabetes;Able to give informed consent and report side effects; Exclusion criteria:Antibiotic treatment;Drugs that control glucose or lipid profiles; Pregnancy or have given birth in the past year or planning pregnancy in the next 6 months;Lactation;Menopause women;Cancer or chemo/radio therapy;Chronic disease;Competitive athletes;Consumption of probiotic products;History of alcohol use;Abnormal thyroid hormone level;PCOD women;Intake of medications that could affect body weight and/or energy expenditure;Family history of T2DM in first degree relatives Allergy to probiotic or dairy products;Anemia;Recent history of large weight fluctuations;Immune compromised conditions; Current use of antihypertensive medications; depression; Prediabetes; Smoking; CVD; Active colitis; Solid organ transplant; Fatty liver

#### Age

From **18 years** old to **50 years** old

#### Gender

Female

#### Phase

2-3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **80**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics committee of Digestive Disease Reaserch Institute

#### Street address

Shariati Hospital, North Kargar Ave.

#### City

Tehran

#### Postal code

#### Approval date

2013-11-02, 1392/08/11

#### Ethics committee reference number

FWA00001331

### Health conditions studied

#### 1

##### Description of health condition studied

Obesity

##### ICD-10 code

E66

##### ICD-10 code description

Obesity due to excess calories

### Primary outcomes

#### 1

##### Description

body weight

##### Timepoint

0 and 12 weeks

##### Method of measurement

balance

### Secondary outcomes

#### 1

##### Description

Waist circumference

##### Timepoint

0 and 12 weeks

##### Method of measurement

meter

#### 2

##### Description

fasting insulin level

##### Timepoint

0 and 12 weeks

##### Method of measurement

ELISA kit

#### 3

##### Description

insulin resistance

##### Timepoint

0 and 12 weeks

##### Method of measurement

HOMA-IR

## 4

### Description

hs-CRP

### Timepoint

0 and 12 weeks

### Method of measurement

ELISA

## 5

### Description

lipid profiles

### Timepoint

0 and 12 weeks

### Method of measurement

autoanalyzer

## 6

### Description

Liver function tests

### Timepoint

0 and 12 weeks

### Method of measurement

Autoanalyzer

## Intervention groups

### 1

#### Description

intervention group: consumption of 400 gram low-fat-probiotic yogurt per day.

#### Category

Behavior

### 2

#### Description

placebo group: consumption of 400 gram low fat conventional yogurt per day.

#### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Novin Diet Clinic

##### Full name of responsible person

Dr.Hamidreza Farshchi

##### Street address

Novin Diet Clinic, 4 floor, Nikan medical building,  
Shariati subway, Shariati Ave

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Novin Diet Clinic

##### Full name of responsible person

Dr.Hamidreza Farshchi

##### Street address

Novin Diet Clinic, 4 floor, Nikan medical building,  
Shariati subway, Shariati Ave.

##### City

Tehran

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Novin Diet Clinic

#### 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

Novin Diet Clinic

##### Full name of responsible person

Dr.Hamidreza Farshchi

##### Position

Dietition & Diabetes

##### Other areas of specialty/work

##### Street address

Novin Diet Clinic, 4 floor, Nikan medical building,  
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##### City

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##### Postal code

##### Phone

+98 21 2226 3002

##### Fax

##### Email

hrfarshchi@gmail.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Novin Diet Clinic

##### Full name of responsible person

Dr. Seyedeh Ameneh Majd

**Position**

Pharmacologist

**Other areas of specialty/work****Street address**

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**City**

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**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*

**Person responsible for updating data****Contact****Name of organization / entity****Full name of responsible person**

Seyedeh Neda Mousavi

**Position**

Ph.D student of Nutrition & Diet Tehrapy

**Other areas of specialty/work****Street address**

Novin Diet Clinic, 4 floor, Nikan medical building,