

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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/m² 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)

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+98 21 2258 9952

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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.

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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

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Novin Diet Clinic

Full name of responsible person

Dr. Seyedeh Ameneh Majd

Position

Pharmacologist

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Fax**Email**

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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**

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