Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 acidophillus 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 glocuse or blood pressure or with abnormal thyroids hormons 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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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
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Person responsible for updating data

Contact
Name of organization / entity
Full name of responsible person
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Position
Ph.D student of Nutrition & Diet Tehrapy
Other areas of specialty/work
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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