Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effects of probiotic supplement with placebo on anthropometric measurements, metabolic syndrome components, gastrointestinal hormones and inflammatory factors in patients with metabolic syndrome in Tehran

Protocol summary

Summary

The aim of this triple blind randomized controlled trial will be theassociation of the effects of probiotic supplement on anthropometric measurements, metabolic syndrome components, gastrointestinal hormones and inflammatory factors in patients with metabolic syndrome. 46 patients aged 25-70,from both sexes, who do not use antibiotic from 1 month before the study and who do not use Insulin, oral contraceptive drugs or corticosteroids, will randomly categorize into intervention or placebo group. The intervention group will consume 2 probiotic capsules (250 mg) product of PROTEXIN, for 3 months. The placebo group will consume placebo capsules, in number and duration similar to intervention group. Both groups will receive a weight loss diet, according to the adjusted ideal body weight. Anthropometric, nutritional, biochemical (fasting blood glucose, lipid profile, hs-CRP, PYY, GLP-1) and blood pressure measurements will done in the beginning and at the end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013111115368N1**
Registration date: **2014-01-03, 1392/10/13**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-01-03, 1392/10/13

Registrant information

Name

Samira Rabiei

Name of organization / entity

Faculty of Nutrition and Food sciences, Shahid Beheshti University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

National Nutrition and Food Sciences Technology Research Institute

Expected recruitment start date

2014-01-10, 1392/10/20

Expected recruitment end date

2014-11-21, 1393/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of probiotic supplement with placebo on anthropometric measurements, metabolic syndrome components, gastrointestinal hormones and inflammatory factors in patients with metabolic syndrome in Tehran

Public title

The effects of probiotic supplement on patients with metabolic syndrome

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: To be volunteer to participate in this study; Patients with diagnosis of metabolic syndrome; Aged 25-70; To have a BMI ≥25kg/m2; Not smoking, pregnant and lactating; Without a diagnosis of thyroid disorders; Not taking medication including: multivitamin-mineral supplements, omega-3, oral contraceptive peel, estrogen, progesterone, corticosteroids or Insulin; Not consuming green tea and fiber powder; Not being a vegetarian or follower of unusual dietary patterns from before the study; Not taking any kind of antibiotic drugs from 1 month before the study. Exclusion criteria: Taking Antibiotic during study; Consuming energy less than 800 or more than 4200 Kcal/day; Consuming less than 2/3 of probiotic supplement; Missing any inclusion criteria during the study.
Age
From **25 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **46**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Nutrition and Food Sciences Technology Research Institute
Street address
Faculty of Nutrition and Food Sciences, No 7, Hafezi street, Farahzadi blvd, Shahrake Gharb.
City
Tehran
Postal code
1981619573
Approval date
2013-12-08, 1392/09/17
Ethics committee reference number
051530

Health conditions studied

1

Description of health condition studied
metabolic syndrome
ICD-10 code
E78, E66,
ICD-10 code description
Disorders of lipoprotein metabolism and other lipidaemias, Obesity, Other specified diabetes mellitusHypertensive heart disease

Primary outcomes

1

Description
Triglycerid
Timepoint
in the begining and after 3 month
Method of measurement
enzymatic method

2

Description
fasting glucose
Timepoint
in the begining and after 3 month
Method of measurement
enzymatic method

3

Description
HDL
Timepoint
in the begining and after 3 month
Method of measurement
enzymatic method

4

Description
waist circumference
Timepoint
in the begining, after 1 month, after 2 month and after 3 month
Method of measurement
meter

5

Description
systolic and diastolic pressure
Timepoint
in the begining and after 3 month
Method of measurement
barometer

6

Description
hs-CRP
Timepoint
in the begining and after 3 month
Method of measurement
ELISA

7

Description
PYY
Timepoint
in the begining and after 3 month
Method of measurement
ELISA

8

Description
GLP-1
Timepoint
in the begining and after 3 month
Method of measurement
ELISA

9

Description
weight
Timepoint
in the begining, after 1 month, after 2 month and after 3 month
Method of measurement
scale

Secondary outcomes

1

Description
Macronutrients intake
Timepoint
in the begining, after 1 month, after 2 months and after 3 months
Method of measurement
food recall questionnaire

2

Description
Cholesterol
Timepoint
in the begining and after 3 months
Method of measurement
enzymatic method

3

Description
energy intake
Timepoint
in the begining, after 1 month, after 2 months and after 3 months
Method of measurement
food recall questionnaire

4

Description
LDL
Timepoint
in the begining and after 3 months
Method of measurement
Friedwald

5

Description
physical activity
Timepoint
in the begining and after 3 months
Method of measurement
physical activity questionnaire

Intervention groups

1

Description
The intervention group will consume 2 probiotic capsules for 3 months(each white capsule has 250 mg weight , by PROTEXIN). This group will receive a weight loss diet, according to the adjusted ideal body weight and they will follow monthly.
Category
Placebo

2

Description
The placebo group will consume 2 placebo capsules for 3 months which will produce by PROTEXIN similar to probiotic capsules, including maltodextrin. This group will receive a weight loss diet, according to the adjusted ideal body weight and they will follow monthly.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
office of the endocrinologists
Full name of responsible person
Samira Rabiei
Street address
Faculty of Nutrition and Food Science Technology, Shahid Beheshti University of Medical Sciences
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Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
National Nutrition and Food Sciences Technology Research Institut
Full name of responsible person
Samira Rabiei
Street address
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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
National Nutrition and Food Sciences Technology Research Institut
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
Faculty of Nutrition and Food Sciences
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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