

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 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 the association 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 be categorized 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 be 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 $\geq 25\text{kg/m}^2$; Not smoking, pregnant and lactating; Without a diagnosis of thyroid disorders; Not taking medication including: multivitamin-mineral supplements, omega-3, oral contraceptive pill, 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 beginning and after 3 month

Method of measurement

enzymatic method

2

Description

fasting glucose

Timepoint

in the beginning and after 3 month

Method of measurement

enzymatic method

3

Description

HDL

Timepoint

in the beginning and after 3 month

Method of measurement

enzymatic method

4

Description

waist circumference

Timepoint

in the beginning, after 1 month, after 2 month and after 3
month

Method of measurement

meter

5

Description

systolic and diastolic pressure

Timepoint

in the beginning and after 3 month

Method of measurement

barometer

6

Description

hs-CRP

Timepoint

in the beginning and after 3 months

Method of measurement

ELISA

7

Description

PYY

Timepoint

in the beginning and after 3 months

Method of measurement

ELISA

8

Description

GLP-1

Timepoint

in the beginning and after 3 months

Method of measurement

ELISA

9

Description

weight

Timepoint

in the beginning, after 1 month, after 2 months and after 3 months

Method of measurement

scale

Secondary outcomes

1

Description

Macronutrients intake

Timepoint

in the beginning, after 1 month, after 2 months and after 3 months

Method of measurement

food recall questionnaire

2

Description

Cholesterol

Timepoint

in the beginning and after 3 months

Method of measurement

enzymatic method

3

Description

energy intake

Timepoint

in the beginning, after 1 month, after 2 months and after 3 months

Method of measurement

food recall questionnaire

4

Description

LDL

Timepoint

in the beginning and after 3 months

Method of measurement

Friedwald

5

Description

physical activity

Timepoint

in the beginning 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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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

Faculty of Nutrition and Food Sciences, Shahid
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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

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

Full name of responsible person

Samira Rabiei

Position

Ph.D,Candidate in Nutrition Sciences

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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