

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Assessment of the effect of probiotic yogurt and regular yogurt consumption on the components, inflammatory and oxidative markers and vascular endothelial function in patients with metabolic syndrome

Protocol summary

Summary

The objective of this randomized double-blind placebo controlled trial is to assess the effect of probiotic yogurt and regular yogurt consumption on the components, inflammatory and oxidative markers and vascular endothelial function in patients with metabolic syndrome. Subjects will be recruited to the study, according to inclusion criteria: ages between 20 to 65 years; diagnosis of the metabolic syndrome based on definition of the Iranian National Committee of Obesity, and exclusion criteria: suffering from cardiovascular disease, renal failure, diabetes mellitus and gastrointestinal diseases; receiving supplements of probiotic during the two months before the study; pregnancy; lactation; menopause. Subjects including 44 individuals from both sexes will be randomly divided into two intervention and control groups, using a blocked randomization procedure of size of 4. Subjects in intervention and control group will receive 300 g daily of probiotic or regular yogurt respectively for 8 weeks. The assignment of groups will cover from the investigators and the subjects. Probiotic and regular yogurt containers will be identical looking and with three-digit code will be separable. Fasting blood samples, blood pressure and anthropometric measurements, appetite questionnaire, physical activity questionnaire, 3 dietary records for each person will be performed at the beginning and end of the study. The levels of markers of inflammatory and oxidative and vascular endothelial function, blood sugar, lipid profile and insulin in the fasting blood samples will be assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608213140N17**
Registration date: **2016-11-09, 1395/08/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-09, 1395/08/19

Registrant information

Name

Bahram Pourghassem Gargari

Name of organization / entity

Health and Nutrition Faculty, Tabriz University of medical sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of probiotic yogurt and regular

yogurt consumption on the components, inflammatory and oxidative markers and vascular endothelial function in patients with metabolic syndrome

Public title

The effect of probiotic yogurt and regular yogurt consumption in patients with metabolic syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Willingness to participate; women and men aged 20-65 years; diagnosis of the metabolic syndrome based on the presence of any 3 of the criteria defined by the Iranian National Committee of Obesity: waist circumference ≥ 95 cm in both genders; fasting serum glucose ≥ 100 mg/dl; serum triglyceride ≥ 150 mg/dl; serum HDL cholesterol < 40 mg/dl in men and < 50 mg/dl in women; systolic blood pressure ≥ 130 mmHg and/or diastolic blood pressure ≥ 85 mmHg. Exclusion criteria: suffering from cardiovascular disease, renal failure, diabetes and gastrointestinal diseases; receiving antibiotics; supplement of vitamin and minerals, fiber, omega-3 and probiotic supplements during the two months before the start of the study; presence of pregnancy or lactation or menopause; extreme sports more than 100 minutes per week; having the weight loss diet the three months before the study; hormone therapy; taking contraceptive drugs; alcohol intake, smoking and tobacco; history of cancer and medical treatment and drugs that affect the neuroendocrine function, metabolism or appetite; thyroid problems; gastrointestinal surgery during the past year; treatment with immunomodulatory drugs one month before the study; chronic use of laxative (more than twice a week).

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Tabriz University of Medical Sciences

Street address

Attar Neyshaboori Street, Golgasht Avenue, Tabriz University of Medical Sciences

City

Tabriz

Postal code

Approval date

2016-08-29, 1395/06/08

Ethics committee reference number

IR.TBZMED.REC.1395.668

Health conditions studied

1

Description of health condition studied

Metabolic Syndrom

ICD-10 code

E88.9

ICD-10 code description

metabolic disorders not specified

Primary outcomes

1

Description

Blood glucose

Timepoint

Begining and end of the intervention

Method of measurement

Enzymatic

2

Description

Insulin, insulin resistance index

Timepoint

Begining and end of the intervention

Method of measurement

ELISA and HOMA-IR formula

3

Description

Lipid profile

Timepoint

Begining and end of the intervention

Method of measurement

Spectrophotometry

4

Description

Blood pressure
Timepoint
Beginning and end of the intervention
Method of measurement
Digital monometer

5

Description
Anthropometry markers
Timepoint
Beginning and end of the intervention
Method of measurement
Stadiometer, scale, tape

6

Description
Tumor Necrosis Factor-Alpha (TNF- α)
Timepoint
Beginning and end of the intervention
Method of measurement
ELISA

7

Description
Interleukin-6 (IL-6)
Timepoint
Beginning and end of the intervention
Method of measurement
ELISA

8

Description
hs-CRP
Timepoint
Beginning and end of the intervention
Method of measurement
Immunoturbidometry

9

Description
Lipopolysaccharides (LPS)
Timepoint
Beginning and end of the intervention
Method of measurement
ELISA

10

Description
Malondialdehyde (MDA)
Timepoint
Beginning and end of the intervention
Method of measurement
Spectrophotometry

11

Description
Total Antioxidant Capacity

Timepoint
Beginning and end of the intervention
Method of measurement
Spectrophotometry

12

Description
Uric Acid
Timepoint
Beginning and end of the intervention
Method of measurement
Enzymatic

13

Description
Oxidized LDL (OxLDL)
Timepoint
Beginning and end of the intervention
Method of measurement
ELISA

14

Description
Plasminogen Activator Inhibitor-1 (PAI-1)
Timepoint
Beginning and end of the intervention
Method of measurement
ELISA

15

Description
Vascular Cell Adhesion Molecule Type 1 (VCAM-1)
Timepoint
Beginning and end of the intervention
Method of measurement
ELISA

16

Description
Intercellular Adhesion Molecule Type 1 (ICAM-1)
Timepoint
Beginning and end of the intervention
Method of measurement
ELISA

Secondary outcomes

1

Description
Appetite
Timepoint
Beginning and end of the intervention
Method of measurement
Appetite Questionnaire (Visual Analogue Scale)

2

Description

Physical activity

Timepoint

Beginning and end of the intervention

Method of measurement

International Physical Activity Questionnaire

3

Description

Energy and macronutrients intake

Timepoint

Beginning and end of the intervention

Method of measurement

Three day dietary record questionnair

Intervention groups

1

Description

Intervention group: 300 g/day probiotic yogurt including Lactobacillus acidophilus La5 and bifidobacterium lactis Bb12 for 8 weeks

Category

Prevention

2

Description

Placebo group: 300 g/day regular yogurt

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Nutrition and Food Sciences, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Pourgasem Gargari

Street address

Attar Neyshaboori Street, Golgasht Avenue, Faculty of Nutrition and Food Sciences, Tabriz University of Medical Sciences

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Rashidi

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Attar Neyshaboori Street, Golgasht Avenue, Tabriz University of Medical Sciences

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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

Vice chancellor for research, Tabriz University of Medical Sciences

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, Tabriz University of Medical Sciences

Full name of responsible person

Leila Rezazadeh

Position

Ph.D candidate of Nutrition

Other areas of specialty/work

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Position

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Faculty of Nutrition and Food Sciences, Tabriz University of Medical Sciences

Full name of responsible person

Leila Rezazadeh

Position

Ph.D candidate of Nutrition

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

Attar Neyshaboori Street, Golgasht Avenue, Faculty of

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