

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Effects of Daily Low-Fat Synbiotic Yogurt Consumption on Metabolic Parameters, Inflammatory Biomarkers, and Gene Expression Related to Inflammation and Lipid in Adults with Metabolic Syndrome

Protocol summary

Study aim

Examining The Effect of a New Developed Synbiotic Yogurt Consumption on Serum Inflammatory Biomarkers and the Expression of NF- κ B and Lipid Metabolism Related Genes in Adults with Metabolic Syndrome

Design

Randomized, double-blind, placebo-controlled clinical trial

Settings and conduct

The intervention will be performed for 12 weeks on people with metabolic syndrome in health centers in Yasuj. People will be given 14 cans of yogurt once every two weeks, and patients will consume a 300-gram can of yogurt daily. The evaluation of variables is done at the beginning and end of the study by sampling the patient's blood.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 30 and 50 years old, body mass index= 25-35 Kg/m², the presence of at least three of the five components of the metabolic syndrome, and willingness to participate in the study. Exclusion criteria: weight changes of more than 10% in the last six months, change in the amount of sports activity, pregnant, lactating, and postmenopausal women, allergy to dairy products and probiotics, smoking and alcohol consumption, routine consumption of probiotic or synbiotic products, suffering from various diseases, taking certain medications such as antibiotics, anti-diabetics, and lipid-lowering drugs, uncontrolled blood pressure, consuming probiotic supplements.

Intervention groups

The subjects in the intervention group will receive 300 g/day of synbiotic yogurt containing Lactobacillus Plantarum, Lactobacillus pentosus (2×10^8 CFU), and the yeast Kluyveromyces marxianus and 3% of natural plants (mountain celery, shallot, chicory, and mint) for 12 weeks. The control group will consume 300 g/day of

regular yogurt. Yasuj Pasteurized Milk Company will provide the yogurts.

Main outcome variables

Serum Inflammatory Biomarkers and the Expression of NF- κ B and Lipid Metabolism Related Genes

General information

Reason for update

It was possible to add new parameters due to the proposal of the statistical and executive consultants of the plan.

Acronym

IRCT registration information

IRCT registration number: **IRCT20170202032367N6**

Registration date: **2022-07-17, 1401/04/26**

Registration timing: **prospective**

Last update: **2024-12-11, 1403/09/21**

Update count: **5**

Registration date

2022-07-17, 1401/04/26

Registrant information

Name

Hossien Imani

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

2022-07-23, 1401/05/01

Actual recruitment end date

2022-12-06, 1401/09/15

Trial completion date

2023-04-04, 1402/01/15

Scientific title

Effects of Daily Low-Fat Synbiotic Yogurt Consumption on Metabolic Parameters, Inflammatory Biomarkers, and Gene Expression Related to Inflammation and Lipid in Adults with Metabolic Syndrome

Public title

The effect of a new developed synbiotic yogurt consumption in adults with metabolic syndrome

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 30 and 50 years old Body mass index (BMI) ranged from 25 to 35 kg/m² The presence of at least three of the five components of the metabolic syndrome according to the ATP III criteria including waist circumference greater than 102 cm in men and 88 cm in women, triglyceride equal to or greater than 150 mg/dL, HDL less than or equal to 40 in men and less than or equal to 50 in women, blood pressure equal to or greater than 130/85 mmHg and blood sugar equal to or greater than 100 mg/dL Willingness to participate in the study

Exclusion criteria:

Participate in weight loss programs over the past six months Weight change of more than 10% in the last six months Professional athletes or changes in the intensity and level of physical activity during the last four weeks Pregnant, lactating and postmenopausal women Allergy to dairy products and probiotics Smoking and alcohol consumption Routine consumption of products containing probiotics or synbiotics Diagnosed cardiovascular, kidney, gastrointestinal, endocrine, pulmonary, neurological, and autoimmune diseases; diabetes; thyroid dysfunction; cancer; and eating disorders. Taking medications that could affect appetite, body weight, and lipid metabolism or have anti-inflammatory effects such as corticosteroids, oral contraceptives, antidepressants and antipsychotics, anti-diabetics, statins, and other lipid-lowering drugs. Take antibiotics one month before the study begins Uncontrolled blood pressure ke probiotics and other dietary supplements within one months before the start of the study

Age

From **30 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **44**

Actual sample size reached: **41**

Randomization (investigator's opinion)

Randomized

Randomization description

First, we will use the Stratified Permuted Block Randomization method for patients who meet the inclusion criteria for random distribution in the intervention and control groups. First, they are classified in terms of gender (male/female) and body mass index level (from 25–29.9 and 35–30) and are placed in double blocks using the randomization method with sizes 2 and 4 (from the special table). used for randomization). Accordingly, each person may have four states. Then, people with the same conditions are randomly divided into intervention and control groups. In order to randomly assign both people to one of the groups, each person will be given a code, and these codes will be poured into a pot. An out-of-study person will then be asked to draw the codes out of the pot using a lottery. The person with the first code issued will be assigned to the intervention group and the other person to the control group. This process will be done in the same way for both people with the same condition.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients enrolled in this study will be unaware of whether they are in the normal yogurt group or in the synbiotic yogurt group. On the other hand, due to the similarity of the appearance of both products, which are given to the participants in packages with the same appearance and the same label, an attempt has been made to blind the patients. Also other people who participate in other stages including the researchers, the outcome evaluators, the analysts are blind to the study, and the third independent person is responsible for prescribing and secretly recording our type of prescription, and the other person is responsible for collecting data. The data analyzer also announces the results according to groups A and B. The drug evaluator also does not know the type of yogurt prescribed for each patient.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Room 605, Sixth Floor, Central Building of Tehran University of Medical Sciences, Qods Street, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653911

Approval date

2022-02-08, 1400/11/19

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1275

Health conditions studied

1

Description of health condition studied

Metabolic syndrome

ICD-10 code

Metabolic

ICD-10 code description

E88.81

Primary outcomes

1

Description

IL-6

Timepoint

Baseline and after 12 weeks of intervention

Method of measurement

ELISA

2

Description

TNF- α

Timepoint

Baseline and after 12 weeks of intervention

Method of measurement

ELISA

3

Description

hs-CRP

Timepoint

Baseline and after 12 weeks of intervention

Method of measurement

Enzymatic

4

Description

Gene expression of PPAR- γ

Timepoint

Baseline and after 12 weeks of intervention

Method of measurement

Real time RT-PCR

5

Description

Gene expression of LDL-R

Timepoint

Baseline and after 12 weeks of intervention

Method of measurement

Real time RT-PCR

6

Description

Gene expression of NF- κ B

Timepoint

Baseline and after 12 weeks of intervention

Method of measurement

Real time RT-PCR

Secondary outcomes

1

Description

Energy and macronutrients intake

Timepoint

Baseline, 6th week, and at the end of the intervention

Method of measurement

Three day dietary recall questionnaire

2

Description

Physical activity

Timepoint

Baseline, 6th week, and at the end of the intervention

Method of measurement

International Physical Activity Questionnaire

3

Description

Serum level of liver enzymes

Timepoint

Baseline and after 12 weeks of intervention

Method of measurement

Enzymatic

4

Description

Creatinine

Timepoint

Baseline and after 12 weeks of intervention

Method of measurement

Enzymatic

5

Description

Urea

Timepoint

Baseline and after 12 weeks of intervention

Method of measurement

Enzymatic

6

Description

Complete blood cells parameters

Timepoint

Baseline and after 12 weeks of intervention

Method of measurement

Cell counter devices

7

Description

Triglycerides

Timepoint

Baseline and after 12 weeks of intervention

Method of measurement

Enzymatic method

8

Description

Total cholesterol (TC)

Timepoint

Baseline and after 12 weeks of intervention

Method of measurement

Enzymatic method

9

Description

high-density lipoprotein cholesterol (HDL-C)

Timepoint

Baseline and after 12 weeks of intervention

Method of measurement

Enzymatic method

10

Description

low-density lipoprotein cholesterol (LDL-C)

Timepoint

Baseline and after 12 weeks of intervention

Method of measurement

Based on Friedwald's formula

11

Description

Fasting blood sugar

Timepoint

Baseline and after 12 weeks of intervention

Method of measurement

Enzymatic method

12

Description

Blood pressure

Timepoint

Baseline and after 12 weeks of intervention

Method of measurement

Mercury monometer

13

Description

Body mass index

Timepoint

Baseline and after 12 weeks of intervention

Method of measurement

Kg/m²

14

Description

Waist circumference

Timepoint

Baseline and after 12 weeks of intervention

Method of measurement

Tape

Intervention groups

1

Description

Intervention group: Will receive 300 g/day of synbiotic yogurt containing Lactobacillus Plantarum, Lactobacillus pentosus (2*10⁸ CFU), and Kluyveromyces marxianus and 3% of various natural plants (mountain celery, shallot, chicory, and mint) made by Yasuj Pasteurized Milk Company for 12 weeks.

Category

Prevention

2

Description

Control group: Will receive 300 g/day of regular yogurt made by Yasuj Pasteurized Milk Company for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Damide Boyer Ahmad Health Center

Full name of responsible person

Mohammad Yazdan-panah

Street address

Boyer Ahmad Health Center, Shahid Dastjerdi alley -
Artesh avenue

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2**Recruitment center****Name of recruitment center**

Yasuj Shahid Beheshti Hospital

Full name of responsible person

Zaker Saeedinejad

Street addressShahid Beheshti hospital, Mohammad Montazeri
avenue**City**

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Phone

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Email

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3**Recruitment center****Name of recruitment center**

Imam Sajjad hospital, Yasuj

Full name of responsible person

Parastou Rad

Street address

Imam Sajjad Hospital, next to Azadi Hotel

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Phone

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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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

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding*empty***Country of origin****Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Hossien Imani

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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**Person responsible for scientific
inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

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Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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

Tehran University of Medical Sciences

Full name of responsible person

Mohammadreza Jowshan

Position

Student

Latest degree

Master

Other areas of specialty/work

Clinical Nutrition

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to confidentiality of participant information, it is not possible to publish it

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable