Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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-κB 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˟108 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-κB 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

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Name of organization / entity
Tehran University of Medical Sciences

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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-κB
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
City
Yasuj

Province
Kohgilouyeh-va-Boyrahmad
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Phone
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Email
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2

Recruitment center
Name of recruitment center
Yasuj Shahid Beheshti Hospital
Full name of responsible person
Zaker Saeedinejad
Street address
Shahid Beheshti hospital, Mohammad Montazeri avenue
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Kohgilouyeh-va-Boyrahmad
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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
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Street address
Imam Sajjad Hospital, next to Azadi Hotel
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Province
Kohgilouyeh-va-Boyrahmad
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7591994799
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parastou.rad@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Central Building of Tehran University of Medical Sciences, Qods Street, Keshavarz Blvd.
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afotouhi@tums.ac.ir
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
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Hossien Imani
Position
Assistant professor
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Other areas of specialty/work
Nutrition
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Person responsible for updating data

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Latest degree
Master
Other areas of specialty/work
Clinical Nutrition
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No. 13 , Raja 10 Alley , Rajaei street
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+98 74 3323 2203
Email
mr-jowshan@razi.tums.ac.ir
Web page address
http://joushan.ir/

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