Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The effect of a new developed synbiotic yogurt consumption on metabolic syndrome components, oxidative stress status, and some other cardiovascular disease risk factors in adults with metabolic syndrome

Protocol summary

Study aim

Examining the effects of using newly designed synbiotic yogurt on metabolic syndrome components, oxidative stress, and some other risk factors for cardiovascular disease 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

Components of metabolic syndrome; Oxidative stress status; Atherogenicity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220426054667N1**
Registration date: **2022-05-18, 1401/02/28**
Registration timing: **prospective**

Last update: **2022-05-18, 1401/02/28**
Update count: **0**

Registration date

2022-05-18, 1401/02/28

Registrant information

Name

Somayyeh Asghari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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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
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of a new developed synbiotic yogurt consumption on metabolic syndrome components, oxidative stress status, and some other cardiovascular disease risk factors 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 Take probiotics and other dietary supplements within three 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**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients who meet the inclusion criteria will be randomly assigned to one of the two intervention groups. Randomization will be carried out using a block randomization procedure of size 2 and 4 stratified by sex (male or female) and BMI (25–29.9 or 30–35 kg/m2). Random allocation software will be used for generating a random sequence.
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
2022-04-20, 1401/01/31
Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.080

Health conditions studied

1

Description of health condition studied
Metabolic syndrome
ICD-10 code
E88.81
ICD-10 code description
Metabolic syndrome

Primary outcomes

1

Description
Fasting blood sugar
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Enzymatic method

2

Description
Insulin
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
ELISA

3

Description
triglycerides
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Enzymatic

4

Description
ApoA1
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Immunoturbidometry

5

Description
ApoB
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Immunoturbidometry

6

Description
ApoA1/ApoB
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Blood concentration ratio ApoA1 / ApoB

7

Description
Atherogenic index of plasma (AIP)
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
logTG/HDL formula

8

Description
Oxidized LDL (Ox-LDL)
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
ELISA

9

Description
Blood pressure
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Mercury monometer

10

Description
weight
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Digital scales

11

Description
Malondialdehyde (MDA)
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Spectrophotometry

12

Description
Superoxide dismutase (SOD)
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Spectrophotometry

13

Description
Glutathione Peroxidase (GPX)
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Spectrophotometry

14

Description
Total Oxidative status (TOS)
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Spectrophotometry

15

Description
Total antioxidant capacity (TAC)
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Spectrophotometry

16

Description
insulin resistance index
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
HOMA-IR formula

17

Description
HDL cholesterol
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Enzymatic

18

Description
Height
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Stadiometer

19

Description
Waist circumference
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
tape

20

Description
Body mass index
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Kg/m2

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

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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Yasuj

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2

Recruitment center

Name of recruitment center
Yasuj Shahid Beheshti Hospital

Full name of responsible person
Zaker Saeedinejad

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Shahid Beheshti hospital, Mohammad Montazeri avenue

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Email
beheshtihospital@yasooj.ir

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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Kohgilouyeh-va-Boyrahmad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Somayyeh Asghari

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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inquiries

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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