

# 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/m<sup>2</sup>, 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<sup>8</sup> 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)

##### Phone

+98 21 8895 5814

##### Email address

sasghari@sina.tums.ac.ir

##### 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/m<sup>2</sup> 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/m<sup>2</sup>). 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**

## 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/m<sup>2</sup>

## **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\*10<sup>8</sup> 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

**Postal code**

7591875114

**Phone**

+98 74 3322 8212

**Email**

yazdanpanahm@gmail.com

**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

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyrahmad

**Postal code**

7591794857

**Phone**

+98 74 3322 4721

**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

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyrahmad

**Postal code**

7591994799

**Phone**

+98 74 3322 0163

**Email**

parastou.rad@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Akbar Fotouhi

**Street address**

Central Building of Tehran University of Medical Sciences, Qods Street, Keshavarz Blvd.

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Phone**

+98 21 8163 3685

**Email**

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

**Full name of responsible person**

Somayyeh Asghari

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

No. 44, Shahid Hojjat Doost Alley, Naderi St, Keshavarz Boulevard

**City**

Tehran

**Province**

Tehran

**Postal code**

1416643931

**Phone**

0098 21 889900285

**Email**

asghari.nut@gmail.com

**Person responsible for scientific**

## **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

**Street address**

No. 44, Shahid Hojjat Doost Alley, Naderi St,  
Keshavarz Boulevard

**City**

Tehran

**Province**

Tehran

**Postal code**

1416643931

**Phone**

0098 21 889900285

**Email**

asghari.nut@gmail.com

## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Amin Zolghadrpour

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

**Street address**

No. 13 , Raja 10 Alley , Rajaei street

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyer-Ahmad

**Postal code**

7591956157

**Phone**

+98 74 3323 2203

**Email**

zolmohamadamin@gmail.com

## **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