

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Evaluating the effect of whey protein, calcium, and vitamin D-fortified synbiotic yogurt compared with low-fat conventional yogurt on anthropometric indices, insulin resistance, lipid profiles, inflammatory markers and appetite status in overweight and obese patients with metabolic syndrome following the balanced hypocaloric diet.

Protocol summary

Summary

This randomized, double-blind, controlled parallel-group RCT was planned to compare the effects of low-fat whey protein, calcium and vitamin D-fortified synbiotic yogurt (FY) consumption with low-fat conventional yogurt (CY) following an energy restricted diet (500- kcal) in overweight and obese subjects with metabolic syndrome. All subjects entered into a 2-wk run-in period before intervention to obtain detailed information about the dietary intakes and physical activity. At the end of run-in period participants were randomly assigned to receive either 2 servings/day (2×250 ml/day) of FY or 2 servings/day (2×250 ml/day) of CY for 10 weeks. The diet program was designed to introduce a 500 kcal energy deficit based on estimated energy requirements at the start of the study. Randomization process was done using blocked randomization. Subjects and investigators were unaware of the participant's group allocation. The primary endpoint was any change in HOMA-IR from baseline at week 10. The secondary endpoints included changes in anthropometric and body composition measures, blood pressure, 25(OH)D3 levels, fasting blood sugar, fasting insulin, QUICKI index, lipids profile, inflammatory markers and appetite status. Anthropometric indices and biochemical assessment were done at the beginning and at the end of the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050633836N1**
Registration date: **2017-07-15, 1396/04/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-07-15, 1396/04/24

Registrant information

Name

Mohsen Mohammadi Sartang

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 3725 1001

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mohamadism@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2016-12-15, 1395/09/25

Expected recruitment end date

2017-05-20, 1396/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of whey protein, calcium, and vitamin D-fortified synbiotic yogurt compared with low-fat conventional yogurt on anthropometric indices, insulin resistance, lipid profiles, inflammatory markers and appetite status in overweight and obese patients with metabolic syndrome following the balanced hypocaloric diet.

Public title

The effect of whey protein, calcium, and vitamin D-fortified synbiotic yogurt in overweight and obese patients with metabolic syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria: aged between 20 and 60 years and a BMI of 25.0–35 kg/m². The metabolic syndrome was diagnosed as having three of the following five features: waist circumference (≥ 102 cm in men and ≥ 88 cm in women); triglyceride levels (≥ 150 mg/dl); HDL-C levels (< 40 mg/dl in men and < 50 mg/dl in women); blood pressure ($\geq 130/85$ mmHg or on treatment for hypertension); glucose levels (≥ 100 mg/dl). The ability to understand the study protocol and provide written informed consent. The exclusion criteria were as follows: an inability or unwillingness to participate; antibiotic treatment; more than 10% weight change over the preceding 6 months; recent (four weeks) changes in exercise intensity or frequency; nonconsumption of low-fat yogurts habitually; consumption of probiotic products habitually; intake of medications that could affect body weight, calcium or vitamin D metabolism; taking drugs for blood glucose or lipid control; taking multivitamin-mineral supplements, omega-3 and oral contraceptive pill; Allergy to probiotic or dairy products; smoking or alcohol consumption; serious medical illnesses including cardiovascular, gastrointestinal, cancer, neurologic, renal, hepatic, endocrine, rheumatoid, thyroid and eating disorders. We also excluded the pregnant or lactating women. We also made sure that the subjects had not participated in any other weight management studies within the last 6 months of screening. Other exclusion criteria during the study included: non-compliance to the study protocol; the occurrence of serious adverse events and any changes in intensity or frequency of exercise.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Shiraz, Iran

City

Shiraz

Postal code**Approval date**

2016-12-14, 1395/09/24

Ethics committee reference number

IR.SUMS.REC.1395.151

Health conditions studied**1****Description of health condition studied**

Obesity

ICD-10 code

E66

ICD-10 code description

Obesity

2**Description of health condition studied**

Metabolic syndrome

ICD-10 code

E88

ICD-10 code description

Other metabolic disorders

Primary outcomes**1****Description**

Homeostasis model assessment of insulin resistance (HOMA-IR)

Timepoint

Pre and 10 weeks after intervention

Method of measurement

Equation

Secondary outcomes

1

Description

Anthropometric indices (weight, waist circumference, BMI)

Timepoint

Pre and post intervention

Method of measurement

Pre and post intervention

2

Description

body composition measurements (Fat mass and fat free mass)

Timepoint

At the beginning and at the end of the study

Method of measurement

BIA

3

Description

Fasting blood glucose

Timepoint

At the beginning and at the end of the study

Method of measurement

Biochemical

4

Description

Serum insulin

Timepoint

At the beginning and at the end of the study

Method of measurement

ELISA

5

Description

Lipid profile (triglycerides (TG), total cholesterol (TC), low density lipoprotein (LDL) and high density lipoprotein (HDL))

Timepoint

At the beginning and at the end of the study

Method of measurement

Enzymatic methods

6

Description

Blood pressure

Timepoint

At the beginning and at the end of the study

Method of measurement

Digital Barometer

7

Description

25 (OH)vit D

Timepoint

At the beginning and at the end of the study

Method of measurement

ELISA

8

Description

Serum MDA

Timepoint

At the beginning and at the end of the study

Method of measurement

TBARS method

9

Description

hs-CRP

Timepoint

At the beginning and at the end of the study

Method of measurement

ELISA

10

Description

serum adiponectin

Timepoint

At the beginning and at the end of the study

Method of measurement

ELISA

11

Description

Endothelin-1

Timepoint

At the beginning and at the end of the study

Method of measurement

ELISA

12

Description

appetite status

Timepoint

At the beginning, at 5 weeks and at the end of the study

Method of measurement

by visual analog scales (VAS)

Intervention groups

1

Description

Intervention group was provided 2 servings/day of FY (2×250 ml/day) plus weight-loss diet for 10 weeks. One serving of FY contained 5 g whey protein, 3 g inulin as prebiotic, 500 mg calcium, 500 IU vitamin D and bifidobacteria as probiotic.

Category

Treatment - Other

2

Description

Control group was provided 2 servings/day of CY (2×250 ml/day) containing *Lactobacillus bulgaricus* and *Streptococcus thermophilus* plus weight-loss diet for 10 weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinics of Shiraz University of Medical Sciences (Motahari and Imam reza) and newspaper advertising

Full name of responsible person

Mohsen Mohammadi Sartang

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Postforosh

Street address

Shiraz University of Medical Sciences, Shiraz, Iran

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical sciences

Full name of responsible person

Mohsen Mohammadi Sartang

Position

PhD Candidate

Other areas of specialty/work

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Professor

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Position

PhD candidate

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Web page address	<i>empty</i>
Sharing plan	Informed Consent Form
	<i>empty</i>
Deidentified Individual Participant Data Set (IPD)	Clinical Study Report
<i>empty</i>	<i>empty</i>
Study Protocol	Analytic Code
<i>empty</i>	<i>empty</i>
Statistical Analysis Plan	Data Dictionary
	<i>empty</i>