Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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, clacium 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

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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); try glycerol levels (≥150 mg/dl); HDL-C levels (<40 mg/dl in men and <50 mg/dl in women); blood pressure (≥130/ 85mmHg 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 peel; 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 perbiotic, 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 thermophile 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty