Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effects of cow milk, fortified soy milk, and calcium supplement on anthropometric indices, adipocytokins, blood pressure, and insulin resistance in premenopaused over weight and obese women

Protocol summary

Summary

In this clinical trial, 100 healthy overweight or obese premenopausal women were randomized to one of the following dietary regimens for 8 weeks: (1) a control diet providing a 500 kcal/day deficit, with 500-600 mg/day dietary calcium; (2) a calcium-supplemented diet identical to the control diet with 800 mg/day of calcium as calcium carbonate; (3) a milk diet providing a 500 kcal/day deficit and containing three servings of low-fat milk; (4) a soy milk diet providing a 500 kcal/day deficit and containing three servings of calcium fortified soy milk. At baseline and after 8 weeks, weight, waist circumference, and hip circumference were measured. Three 24-h dietary records and physical activity records were also taken.

General information

Acronym

Effect of calcium and milk on weight loss and insulin resistance

IRCT registration information

IRCT registration number: **IRCT2013042113080N1**
Registration date: **2013-05-13, 1392/02/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-05-13, 1392/02/23

Registrant information

Name

Shiva Faghih

Name of organization / entity

Shiraz University of Medical Sceinces

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Institute of Nutrition and Food Technology Research

Expected recruitment start date

2009-01-19, 1387/10/30

Expected recruitment end date

2009-06-22, 1388/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of cow milk, fortified soy milk, and calcium supplement on anthropometric indices, adipocytokins, blood pressure, and insulin resistance in premenopaused over weight and obese women

Public title

Effect of calcium and dairy product on weight loss

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria were as follows: body mass index (BMI) more than 25 kg/m2 (range 25-40); taking no medications or supplements which might affect metabolism of calcium, vitamin D or weight loss; absence of menopause; stable body weight (body weight change less than 3 kg for the last 2 months); absence of coronary-artery disease, diabetes, hypertension, thyroid,

and kidney diseases. The subjects were not pregnant and non-lactating with no allergy to milk or soy milk and were not lactose intolerance.

Age
From **20 years** old to **50 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Institute of nutrition and food technology research

Street address
farahzad- arghavan- school of nutrition

City
tehran

Postal code

Approval date
2009-01-03, 1387/10/14

Ethics committee reference number
024342

Health conditions studied

1

Description of health condition studied
overweight

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
weight

Timepoint
2 month

Method of measurement
scale

Secondary outcomes

1

Description
lipid prophile

Timepoint
2 month

Method of measurement
serum lipids

2

Description
insulin resistance

Timepoint
2 month

Method of measurement
HOMA-IR

Intervention groups

1

Description
(a) a control diet which has 500-kcal/day reduction in energy.

Category
Other

2

Description
a calcium-supplemented diet containing 800 mg/day calcium carbonate and 500kcal/day energy reduction

Category
Treatment - Drugs

3

Description
a high-milk diet containing three servings of low-fat milk and 500kcal/day energy reduction

Category
Treatment - Drugs

4

Description
a soy-milk diet containing three servings of calcium-fortified soy milk and -500kcal/day

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Nutrition- Shahid Beheshti University of Medical Sciences

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Institute of Nutrition and Food Technology Research

Full name of responsible person

Dr Hedayat Hoseini

Street address

Farahzad- Arghavan

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Institute of Nutrition and Food Technology Research

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

Shiva Faghih

Position

Assisstant professor

Other areas of specialty/work

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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*