

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Effect of soy flour enriched bread consumption or regular weight loss diet on anthropometric indices, blood pressure and serum lipid profile and its association with apoE genotype in over weight/ obese women: a randomized controlled trial.

Protocol summary

Summary

Design: cross-over clinical trial. Participants: 30 girl students with overweight and obesity. Objective: Evaluation the effects of soy bread consumption on cardiovascular disease risk factor and anthropometric indices and its association with apoE genotype. Inclusion criteria: overweight or obese females. Exclusion criteria: use of specific drugs or supplements, allergy to soya. Setting and conduct: After a 2 week run-in period, all the participants will receive a weight loss diet then participants will be randomly assigned to soy bread and regular diet each for 6 weeks. After 3 weeks washout period, the second phase will be started. Then the participants will be crossed over to the alternate group for additional 6 weeks. To assess the compliance of the participants, every two week a 3 day dietary record and a 3 day physical activity record will be taken. Anthropometric measurements and biochemical assessments including serum triglyceride, total-cholesterol, low density lipoprotein (LDL-C) and high density lipoprotein cholesterol (HDL-c) levels will be measured at the beginning and end of each phases. apoE genotype will be determined at the beginning of the study. Interventions: First the individual energy requirements will be calculated. Then of calculated calorie 300-500 calorie will be reduced for weight loss. The target macro nutrient composition for all participants will be 50-60% of energy as carbohydrate, 15-20% of energy as protein and less than 30% of energy as fat. Women in the soy bread group were asked to replace 120 gr of soy bread with the equal amount of their usual bread intake.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013073114237N1**

Registration date: **2013-09-05, 1392/06/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-09-05, 1392/06/14

Registrant information

Name

Elham Sharifi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

elham_sharifi@nutr.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2012-09-28, 1391/07/07

Expected recruitment end date

2012-11-04, 1391/08/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of soy flour enriched bread consumption or regular weight loss diet on anthropometric indices, blood pressure and serum lipid profile and its association with apoE genotype in over weight/ obese women: a randomized controlled trial.

Public title

Effect of soy flour enriched bread on cardiovascular diseases

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria were; female at age range of 19-35 years old; body mass index (BMI) between 25 and 35; no history of any chronic or acute diseases including; diabetes, CVD, hepatic diseases, renal diseases, cancer; not adherence to a specific diet or other medically prescribed diet no lactation and no pregnancy; no consumption of drugs and dietary supplements. Exclusion criteria: not adherence to the study protocol; use of specific drugs or supplementation; smoking; incidence of chronic diseases such as cardiovascular diseases and allergy to soya.

Age

From **19 years** old to **35 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jerib Avenue

City

Isfahan

Postal code

8174673461

Approval date

2012-11-14, 1391/08/24

Ethics committee reference number

391432

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

High Density Lipoprotein

Timepoint

Week2, Week8, Week11, Week17

Method of measurement

mg/dl, Direct enzymatic method

2

Description

Low Density Lipoprotein

Timepoint

Week2, Week8, Week11, Week17

Method of measurement

mg/dl, Friedewald equation

3

Description

Serum total cholesterol levels

Timepoint

Week2, Week8, Week11, Week17

Method of measurement

mg/dl, Enzymatic method

4

Description

Serum triglyceride levels

Timepoint

Week2, Week8, Week11, Week17

Method of measurement

mg/dl, Enzymatic method

5

Description

ApoE genotype

Timepoint

Week2

Method of measurement

PCR method

Secondary outcomes

1

Description

Weight

Timepoint

baseline, Week2, Week8, Week11, Week17

Method of measurement

Kilogram, Scale

2

Description

Body Mass Index

Timepoint

Baseline, Week2, Week8, Week11, Week17

Method of measurement

kg/m², Weight/Height square

3

Description

Waist circumference

Timepoint

Week 2, Week 8, Week 11,Week17

Method of measurement

meter, centimeter

4

Description

Hip circumference

Timepoint

Week 2, Week 8, Week 11, Week 17

Method of measurement

meter, centimeter

5

Description

Body composition

Timepoint

Week2, Week8, Week11, Week17

Method of measurement

Body Analyser systeme

6

Description

Systolic blood pressure

Timepoint

Week 2, Week 8, Week 11, Week 17

Method of measurement

Sphygmomanometer

7

Description

Diastolic blood pressure

Timepoint

Week 2, Week 8, Week 11, Week 17

Method of measurement

Sphygmomanometer

Intervention groups

1

Description

Soy bread group: energy requirement will be calculated according to equations suggested by the Institute of Medicine, Food and Nutrition Board. for weight loss 300-500 calorie of calculated energy will be reduced . person in this intervention were asked to replace 120gr of soy bread with usual bread intake or other cereal. macronutrient composition for all participants will be 50-60% as carbohydrate, 15-20% as protein and <30% as fat.

Category

Treatment - Other

2

Description

Usual diet: energy requirement for each participant will calculated based on equations suggested by the Institute of Medicine, Food and Nutrition Board. 300-500 calorie will reduced for weight loss. subject in this diet will asked to continue their usual bread intake and other cereal products and not to consume soy product. macronutrient composition in this group is similar to the soy bread group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan University of Medical Sciences

Full name of responsible person

Mohammad Hassan Entezari

Street address

Isfahan University of Medical Sciences, Hezar Jerib Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Isfahan University of Medical Sciences

Full name of responsible person

Dr. Payman Adibi

Street address

Isfahan University of Medical Sciences, Hezar Jerib Avenue

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Isfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research, Isfahan 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**

Department of Clinical Nutrition, School of Nutrition and Food Science, Isfahan University of Medical Sciences

Full name of responsible person

Elham Sharifi Zahabi

Position

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Web page address**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