

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

The Effects of Soy-nut and Soy-protein on the Features of Metabolic Syndrome among Elderly Women in Babol, Iran

Protocol summary

Summary

This is a 12 week interventional study to assess the effect of two soy kinds on the metabolic syndrome features. 75 postmenopausal women, aged 60-70 years, with BMI 18.5-29 and at least three criteria of diagnostic criteria of MS based on NCEP-ATP III definition will be recruited. Patients who are under treatment for ischemic heart disease, hyper or hypothyroidism, kidney or liver diseases and any cancer, have any history of CVD, problem in hearing and mental and allergic reaction to soy consumption will be excluded. Individuals will be randomly divided to three groups (soy-protein, soy-nut and control (25 samples for each group)) and will receive treatment for three months. The primary outcomes are the laboratory tests for assessment of metabolic syndrome features, blood pressure and anthropometric indexes. The secondary outcomes are diet intake record, physical activity, demographic characteristics and health status history.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138804212130N1**
Registration date: **2009-10-20, 1388/07/28**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2009-10-20, 1388/07/28

Registrant information

Name

Afsaneh Bakhtiari

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences.

Expected recruitment start date

2009-07-23, 1388/05/01

Expected recruitment end date

2009-10-23, 1388/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of Soy-nut and Soy-protein on the Features of Metabolic Syndrome among Elderly Women in Babol, Iran

Public title

Soy and metabolic Syndrome

Purpose

Other

Inclusion/Exclusion criteria

Inclusion Criteria: Women, age 60-70 years, BMI between 18.5-29, having at least three criteria of diagnostic criteria of MS, diagnosis of Metabolic syndrome according to the latest update of ATP-III (1. Waist circumference \geq 80 cm 2. TG \geq 150 mg/dl 3. HDL $<$ 50 mg/dl 4. FPG \geq 101 mg/dl 5, blood pressure \geq 130/85) Exclusion criteria: Current or previous estrogen therapy (in the preceding 6 mo), use of soy products or supplements (at least once per week for last 3 month), treatment with insulin or oral hypoglycemic, antilipemic,

or hypertensive agents, treatment for Ischemic heart disease, vegetarian diet (more than six months), smoking (for 3 mo), antibiotic therapy (for last 3 month), documented hyper or hypothyroidism, presence of kidney or liver diseases, breast cancer or any other cancer, the history of CVD, in hearing or mental problem (not able to establish a communication), or allergy to soy

Age

From **60 years** old to **70 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **75**

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

Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganj Afrooz Ave, Babol , Mazandaran, Iran.

City

Babol

Postal code

4717641367

Approval date

empty

Ethics committee reference number

304434/پ/ز

Health conditions studied

1

Description of health condition studied

Metabolic Syndrome

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease

2

Description of health condition studied

Metabolic Syndrome

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

3

Description of health condition studied

Metabolic Syndrome

ICD-10 code

I11

ICD-10 code description

Hypertensive heart disease

Primary outcomes

1

Description

Weight

Timepoint

Before starting the intervention and then monthly for three month until the end of intervention

Method of measurement

Body weight will be measured in kilogram unit while the participants are minimally clothed without shoes by using digital scales and record to the nearest 100 g.

2

Description

Waist circumference

Timepoint

Before starting the intervention and then monthly for three month until the end of intervention

Method of measurement

Waist circumference will be measured in centimeter unit to the nearest value to 0.1 cm and at the narrowest level of waist, in the end of expiration.

3

Description

Hip circumference

Timepoint

Before starting the intervention and then monthly for three month until the end of intervention

Method of measurement

Hip circumference is measured in centimeter at the maximum level over light clothing, by using an unscratched tape measure, without any pressure to body surface

4

Description

Body Mass Index (BMI)

Timepoint

Before starting the intervention and then monthly for three month until the end of intervention

Method of measurement

BMI is calculated in kg/m² unit as weight (in kg) divided by height (in m²).

5

Description

Sub scapula Skin fold (SSF)

Timepoint

Before starting the intervention and then monthly for three month until the end of intervention

Method of measurement

SSF determines the amount of fat storage of sub cutaneous. SSF will be measured in centimeter in sub scapula area by Caliper tool. Every measurement will be repeated three times and the mean of them will be considered. Then SSF will be compared to standard tables .

6

Description

Blood Pressure

Timepoint

Before starting the intervention and then monthly for three month until the end of intervention

Method of measurement

Blood Pressure will be measured in Mm/Hg unit, twice at the right arm after the participants sit for 15 min, by using a standard mercury sphygmomanometer calibrated. The average of two measurements will be used for data analysis. If the first measurements differ by more than 5 mmHg, additional readings will be obtained.

7

Description

Lipid profile (LDL-C, HDL-C, Total cholesterol, TG)

Timepoint

Before starting the intervention and at the end of the intervention

Method of measurement

Serum concentration of lipid profil will be measured in Mg/dl unit using commercially available enzymatic reagents adapted to a Hitachi autoanalyzer.

8

Description

Insulin

Timepoint

Before starting the intervention and at the end of the intervention

Method of measurement

Insulin serum concentration will be measured in µIU/ml unit by using ELISA method.

9

Description

Insulin resistance

Timepoint

Insulin resistanceBefore starting the intervention and at the end of the intervention will be measured before starting the intervention and after end of the intervention (in the third month).

Method of measurement

Insulin resistance will be calculated by using the homeostasis model of assessment insulin resistance (HOMA-IR) according to this formula: Glucose x Insulin/405

10

Description

Apolipoprotein B100 and apoA-I

Timepoint

Before starting the intervention and at the end of the intervention

Method of measurement

Apolipoprotein B100 and apoA-I serum concentrations will be measured in g/l unit by ELISA method. In this study will be used standard and control solutions for all measurements.

11

Description

CRP

Timepoint

Before starting the intervention and at the end of the intervention

Method of measurement

CRP serum concentration will be measured in Mg/dl unit by using ELISA method by Selectra machine.

12

Description

Malondialdehyde (MDA)

Timepoint

Before starting the intervention and at the end of the intervention

Method of measurement

MDA serum concentration will be measured in nmol/l unit on basis HPLC method and using the established thiobarbituric acid (TBARS) method.

13

Description

Blood glucose

Timepoint

Before starting the intervention and at the end of the intervention

Method of measurement

Glucose serum concentration is measured in Mg/dl unit on the day of blood collection by an enzymatic colorimetric method by using glucose oxidase.

14

Description

Total antioxidant capacity (TAC)

Timepoint

Before starting the intervention and at the end of the intervention

Method of measurement

TAC serum concentration will be measured in nmol/l unit by FRAP methode.

Secondary outcomes

1

Description

Food intake status

Timepoint

Before starting the intervention and then monthly for three month until the end of intervention

Method of measurement

Food intake status will be assessed by 3-d diet record questionnaire.

2

Description

Physical activity

Timepoint

Before starting the intervention and then monthly for three month until the end of intervention

Method of measurement

Physical activity will be assessed by IPAQ questionnaire. This questionnaire will be completed in the forth week of every month for 7 days.

Intervention groups

1

Description

Soy protein, 35 grams, once per day for three months, (Soy protein will be delivered to individuals in 490 grams packages with special tool for measurement for consumption of two weeks)

Category

Treatment - Drugs

2

Description

Soy-nut, 35 grams, once per day for three months, (Soy-nut will be delivered to individuals in 490 gm packages for two weeks consumption)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rural health centers and health houses affiliated to Babol University

Full name of responsible person

Afsaneh Bakhtiari

Street address

Babol University of Medical Sciences

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Amroallah Mostafazadeh

Street address

Babol University of Medical Sciences

City

Babol

Grant name

-

Grant code / Reference number

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

Yes

Title of funding source

Babol 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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Afsaneh Bakhtiari

Position

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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