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 Bakhtiary
Name of organization / entity
Babol University of Medical Sciences
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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 ≥ 80 cm 2. TG ≥ 150 mg/dl 3. HDL < 50 mg/dl 4. FPG ≥ 101 mg/dl 5, blood pressure ≥ 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/ژ/پ

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 × 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Dr. Amroallah Mostafazadeh
Street address
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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
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Afsaneh Bakhtiari
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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