

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of soy bean consumption on serum lipid profiles and blood pressure on students and members of Isfahan University of Medical sciences aged 18-45

Protocol summary

Summary

The aim of this study is to evaluate the effect of soy consumption on risk factors of cardiovascular diseases. Two groups were defined for this 6- week parallel randomized clinical trial and healthy youth individuals are randomly recruited in each group: 1- non-intervention group in which subjects were recommended to maintain usual diet and physical activity. 2- intervention group in which which subjects were recommended to maintain usual diet and physical activity plus 75 gr soy bean. poor compliance to recommendations are considered as an exclusion criteria. according to the formula for estimating required sample size for parallel studies, 27 subjects were enrolled to each group. Body weight, waist circumference, blood pressure and lipid profile were measured at baseline and after 6 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013090314551N1**

Registration date: **2013-12-11, 1392/09/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-12-11, 1392/09/20

Registrant information

Name

Mohammad Hossein Rouhani

Name of organization / entity

Country

Iran (Islamic Republic of)

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s_m_rouhani2003@yahoo.com

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2007-09-01, 1386/06/10

Expected recruitment end date

2008-03-30, 1387/01/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of soy bean consumption on serum lipid profiles and blood pressure on students and members of Isfahan University of Medical sciences aged 18-45

Public title

Soy and cardiovascular risk factors

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Aged 18-45; no special medication use; no dietary supplementation use; be healthy; diastolic blood pressure and systolic blood pressure were 60-80 and 100-13, respectively; no compliance to a specific diet and no smoking. Exclusion criteria: failure to complete or timely use of soybeans during the intervention period; reluctance to cooperate and necessity use of medication during the intervention period

Age
From **18 years** old to **45 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical sciences

Street address

Isfahan-Azadi sq.-Hezar jerib St.

City

Isfahan

Postal code

8174673461

Approval date

2007-08-26, 1386/06/04

Ethics committee reference number

286019

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

2

Description of health condition studied

blood pressure

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

3

Description of health condition studied

lipid profile

ICD-10 code

E78

ICD-10 code description

Disorders of lipoprotein metabolism and other lipidaemias

Primary outcomes

1

Description

high density lipoprotein

Timepoint

before the intervention and 6 weeks after intervention

Method of measurement

mg/dl - laboratory

2

Description

low density lipoprotein

Timepoint

before the intervention and 6 weeks after intervention

Method of measurement

mg/dl - laboratory

3

Description

triglyceride

Timepoint

before the intervention and 6 weeks after intervention

Method of measurement

mg/dl - laboratory

4

Description

total cholesterol

Timepoint

before the intervention and 6 weeks after intervention

Method of measurement

mg/dl - laboratory

5

Description

weight

Timepoint

before the intervention and 6 weeks after intervention

Method of measurement

kg - standard scale

6

Description

height

Timepoint

before the intervention and 6 weeks after intervention

Method of measurement

cm - tape

7**Description**

waist circumference

Timepoint

before the intervention and 6 weeks after intervention

Method of measurement

cm - tape

8**Description**

systolic blood pressure

Timepoint

before the intervention and 6 weeks after intervention

Method of measurement

mmHg - standard sphygmomanometer

9**Description**

diastolic blood pressure

Timepoint

before the intervention and 6 weeks after intervention

Method of measurement

mmHg - standard sphygmomanometer

Secondary outcomes**1****Description**

decreasing in total cholesterol, triglyceride, VLDL-C, LDL-C and blood pressure levels and increasing in HDL-C levels

Timepoint

before the intervention and 6 weeks after intervention

Method of measurement

total cholesterol, triglyceride, VLDL-C and HDL-C levels are measured enzymatically by using standard kits with autoanalyzer, LDL-C levels are calculated by using the Friedewald equation, blood pressure is measured by using a standard sphygmomanometer

Intervention groups**1****Description**

intervention group: subjects were recommended to follow their usual diet and physical activity. moreover, they were suggested to intake 75 gr soy bean daily.

Category

Other

2**Description**

Control group: subjects were recommended to follow their usual diet and physical activity. no other intervention was implemented.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Isfahan University of Medical Sciences

Full name of responsible person

Mansoreh Amirpour

Street address**City**

Isfahan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Dr.Gholamhosein Sadri

Street address

Isfahan University of Medical Sciences - Azadi Square

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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

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**

Isfahan University of Medical Sciences

Full name of responsible person

Mehdi Shayanfar

Position

Master of Science

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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