Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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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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 - labratory

2

Description
low density lipoprotein
Timepoint
before the intervention and 6 weeks after intervention
Method of measurement
mg/dl - labratory

3

Description
triglyceride
Timepoint
before the intervention and 6 weeks after intervention
Method of measurement
mg/dl - labratory

4

Description
total cholesterol
Timepoint
before the intervention and 6 weeks after intervention
Method of measurement
mg/dl - labratory

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 cholestrol, 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 cholestrol, 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
City
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
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Mehdi Shayanfar
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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