Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Effect of soymilk consumption on inflammation, fibrinolytic and cardiovascular risks among overweight and obese female adults

Protocol summary

Summary

We evaluated the effects of soy milk compared to caw's milk on inflammation and cardiovascular risk factors among over weight and obese female adults. This was a cross-over randomized clinical trial on 24 subjects. 24 non-menopausal women in the age range of 20 to 50 years and body mass index more than 25 kg/m2 participated in this research. All of them were on a weight reducing diet. Having allergy to soy product or caw's milk and incidence of chronic or acute diseases were exclusion criterias. There were two trial periods for four weeks (soy milk period and caw's milk period) and a washout period for 2 weeks. In the soy milk period only one glass of soy milk (240 cc) was replaced instead of one glass of caw's milk (240 cc). In this research antropometric Indicators, inflammatory markers, liver enzymes, blood pressure, lipid profiles, and glycemic control indice evaluated after soy milk period and caw's milk period .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107052839N3**
Registration date: **2011-08-15, 1390/05/24**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-08-15, 1390/05/24

Registrant information

Name

Leila Azadbakht

Name of organization / entity

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Country

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Recruitment status

Recruitment complete

Funding source

Tehran univercity of medical science, Esfahan univercity of medical science

Expected recruitment start date

2010-09-06, 1389/06/15

Expected recruitment end date

2011-07-06, 1390/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of soymilk consumption on inflammation, fibrinolytic and cardiovascular risks among overweight and obese female adults

Public title

Effect of soymilk on cardiovascular risk factors

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Non-menopausal women in the age range of 20 to 50 years; Body Mass Index more than 25 kg/m2; Not having allergy to soy product or caw's milk; Not incidencing of chronic or acute diseases ; Consume the medications; Following the research protocol exclusion criteria: Non-menopausal women in the age range of more than 50 years; Body Mass Index less than

25 kg/m2; Having allergy to soy product or caw’s milk; Incidence of chronic or acute diseases ; Beginning to consume the medications; Not following the research protocol

Age
From **18 years** old to **50 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 Commitee Of Esfahan Univercity Of Medical Science

Street address
Esfahan univercity of medical science

City
Esfahan

Postal code

Approval date
2011-02-04, 1389/11/15

Ethics committee reference number
289249

Health conditions studied

1

Description of health condition studied
Obesity and overweight

ICD-10 code
e66.0

ICD-10 code description
Obesity due to excess calories

Primary outcomes

1

Description
milk soy

Timepoint
At the begining of the study and 4th,6th,10th weeks

Method of measurement
food record

Secondary outcomes

1

Description
bmi, whr,weight,height,waist circumference,SBP,DBP

Timepoint
At the begining of the study and 4th,6th,10th weeks

Method of measurement
barometer, digital scales, meter

2

Description
crp، il-6

Timepoint
At the begining of the study and 4th,6th,10th weeks

Method of measurement
biochemical test

3

Description
FBS, LDL, TG, Total cholesterol, HDL

Timepoint
At the begining of the study and 4th,6th,10th weeks

Method of measurement
biochemical test

4

Description
ALT،AST، Fibrinogen، Insulin

Timepoint
At the begining of the study and 4th,6th,10th weeks

Method of measurement
biochemical test

Intervention groups

1

Description
One group had to use diet with soy milk in one period of trial for four weeks. The wash-out period was two weeks. In second intervention had to use diet with cows milk for four weeks.

Category
Other

2

Description
another group had to use diet with cows milk in one period of trial for four weeks. The wash-out period was two weeks. In second intervention had to use diet with soy milk for four weeks.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Univercity Of Medical Sciences
Full name of responsible person
Street address
Isfahan Univercity Of Medical Sciences
City
Esfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran Univercity Of Medical Sciences, Isfahan Univercity Of Medical Sciences
Full name of responsible person
Leila Azadbakht
Street address
Department Of Community Nutrition, School Of Nutrition And Food Science, Isfahan University Of Medical Sciences
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran Univercity Of Medical Sciences, Isfahan Univercity 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 Univercity Of Medical Sciences
Full name of responsible person
Leila Azadbakht
Position
Associate Professor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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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