Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of legume consumption on serum adiponectin level, inflammatory biomarkers and cardiovascular risk factors in healthy first degree relatives of diabetic patients

Protocol summary

Summary

The objective of this study is to investigate the effect of legume consumption on serum adiponectin level, inflammatory biomarkers and cardiovascular risk factors in healthy first degree relatives of diabetic patients. Adults aged more than 30 years who are the healthy first degree relatives of diabetic patients are included. The subjects not following the legume consumption will be excluded. The requirement sample size is 19 subjects. This cross-over study will be conducted in 14 weeks that including two 6-weeks and one 2-weeks wash-out period. At the beginning of study, one group randomly assigned to legume packages and one group assigned to healthy recommendations and at the next course, the two groups will be crossed over. At the beginning and end of each period, anthropometric indices, blood pressure, inflammatory markers, adiponectin, lipid profiles, fasting blood glucose and hemoglobin A1C will be assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306212839N5**
Registration date: **2013-07-01, 1392/04/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-07-01, 1392/04/10

Registrant information

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2012-07-22, 1391/05/01

Expected recruitment end date

2012-09-20, 1391/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of legume consumption on serum adiponectin level, inflammatory biomarkers and cardiovascular risk factors in healthy first degree relatives of diabetic patients

Public title

Effect of legume consumption on cardiovascular risk factors

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age more than 30 years, lack of pregnancy and lactation, no history of liver and kidney diseases, cancers, allergies, hypo- and hyperthyroidism, gastrointestinal problems (bloating and irritable bowel

syndrome) and psychosomatic problems. Not using of anti-inflammatory drugs (corticosteroids) and blood glucose lowering drugs (Metformin and Insulin). Not changes in body weight more than 3 kilograms during last two months. Not cigarette smoking. Not following a particular diet. Exclusion criteria: Not using recommended amounts of legumes, not following the research protocol, beginning to consume particular medications during the study, beginning to cigarette smoking during the study, being pregnant during the study, incidence of liver and kidney diseases, kidney stones, cancers, allergies, hypo- and hyperthyroidism, gastrointestinal problems (bloating and irritable bowel syndrome), trauma, surgery and psychosomatic problems during the study. To start Insulin use or blood glucose lowering drugs (Metformin) during the study, change in type and dosage of medications during the study.

Age
From **30 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **19**

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 Isfahan university of medical sciences

Street address
Azadi square, Hezar jarib street, Isfahan university of medical sciences

City
Isfahan

Postal code

Approval date
2012-02-19, 1390/11/30

Ethics committee reference number
191015

Health conditions studied

1

Description of health condition studied
family history of diabetes

ICD-10 code
Z83.3

ICD-10 code description
Family history of diabetes mellitus

Primary outcomes

1

Description
Blood pressure, weight, waist circumference, BMI, total cholesterol, HDL, LDL, TG, FBS, Hb A1C

Timepoint
at the begining of study and weeks 6, 8, 14

Method of measurement
manometer, scale, inelastic tape, biochemical tests

Secondary outcomes

1

Description
IL-6, TNF, hs-CRP, adiponectin

Timepoint
at the begining of atudy and 6th, 8th and 14th week

Method of measurement
biochemical tests

Intervention groups

1

Description
intervention group: packs of legumes (60 grams), 4 time per week, for 6 week

Category
Lifestyle

2

Description
control group: healthy dietary recommendations, for 6 weeks

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan Endocrine and Metabolism Research Center

Full name of responsible person

Street address

City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan university of medical sciences
Full name of responsible person
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Isfahan, Azadi square, Hezar jarib street, Isfahan university of medical sciences, school of nutrition and food sciences
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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

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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