

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 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

##### Name

Leila Azadbakht

##### Name of organization / entity

Nutrition department, School of health, Isfahan

University of Medical Sciences, Isfahan, Iran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1792 2719

##### Email address

azadbakht@hlth.mui.ac.ir

##### 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 Committee 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**

Leila Azadbakht

**Street address**

Isfahan, Azadi square, Hezar jarib street, Isfahan university of medical sciences, school of nutrition and food sciences

**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**

Isfahan university of medical sciences

**Full name of responsible person**

Sahar Saraf-Bank

**Position**

MSc

**Other areas of specialty/work**

**Street address**

Isfahan university of medical sciences, school of nutrition and medical sciences

**City**

Isfahan

**Postal code**

**Phone**

+98 31 1792 2776

**Fax**

**Email**

saraf2shr@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Isfahan university of medical sciences

**Full name of responsible person**

Leila Azadbakht

**Position**

Associate Professor

**Other areas of specialty/work**

**Street address**

Isfahan university of medical sciences, school of nutrition and food sciences

**City**

Isfahan

**Postal code**

**Phone**

+98 31 1792 2776

**Fax**

**Email**

azadbakh@hlth.mui.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Isfahan university of medical sciences

**Full name of responsible person**

Leila Azadbakht

**Position**

Associate Professor

**Other areas of specialty/work**

**Street address**

Isfahan university of medical sciences, school of nutrition and food sciences

**City**

Isfahan

**Postal code**

**Phone**

+98 31 1792 2776

**Fax**

**Email**

azadbakht@hlth.mui.ac.ir

**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*