Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Effect of legumes intake on the lipid profile, stress oxidative and inflammatory markers in insulin resistance

Protocol summary

Summary

The aim of this study was to determine the effect of legume intake on lipid profiles, stress oxidative and inflammatory markers in insulin resistance subjects. 30 insulin resistance subjects participate. Insulin resistance defined as Homeostasis model assessment of insulin resistance (HOMA-IR)> 4.65. Inclusion criteria are body mass index 25-30 Kg/m2 and intake of 2 or lower serving/wk of legumes and exclusion criteria is intake of antioxidant and multivitamin supplement. After 3 weeks of run-in period on a usual diet, we randomly assigned subjects to three interventional groups: control diet including Therapeutic Lifestyle Change or TLC (A diet), TLC diets with 1 ser/d of legumes intake that legume replace with meat intake (B diet), or TLC diet with 3 ser/d of legumes intake that replace with meat intake (C diet), each one for 8 weeks. Each subject followed the three diets and had two washout periods, each washout for 4 weeks. 6 different models were in this study including ABC, ACB, BCA, CBA, BAC, and CAB. Blood samples were drawn at baseline and end of interventions and washout period and biochemical index measure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202251640N7**
Registration date: **2012-03-19, 1390/12/29**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-03-19, 1390/12/29

Registrant information

Name

Parvin Mirmiran

Name of organization / entity

Obesity Research Center, Research Institute for Endocrine Sciences, Shahid Beheshti University of Me

Country

Iran (Islamic Republic of)

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+98 21 2243 2500

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Recruitment status

Recruitment complete

Funding source

Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2012-07-22, 1391/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of legumes intake on the lipid profile, stress oxidative and inflammatory markers in insulin resistance

Public title

Evaluation of legumes intake effects on the lipid profile, stress oxidative and inflammatory markers in insulin resistance

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: subjects aged 16-80 years; no changes in weight over the past 3 months; consumption of 2 or less serving of legumes per week; no specific diet; body

mass index 25-30 kg/m2. Exclusion criteria: hepatic, renal and gastrointestinal diseases, allergy, diabetes mellitus, hyperlipidemia; take of antioxidants and multivitamins-minerals supplementation

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **35**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences

Street address
No 24, Parvaneh st., Yemen Blvd., Chamran exp.

City
Tehran

Postal code

Approval date
2012-02-22, 1390/12/03

Ethics committee reference number
393

Health conditions studied

1

Description of health condition studied
Insulin resistance

ICD-10 code
R73.0

ICD-10 code description
Abnormal glucose tolerance test

2

Description of health condition studied
Insulin resistance

ICD-10 code
E10

ICD-10 code description
Insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Glucose

Timepoint
Baseline, 8 and 12 weeks after intervention

Method of measurement
Biochemical analysis

2

Description
Insulin

Timepoint
Baseline, 8 and 12 weeks after intervention

Method of measurement
Biochemistery analysis

3

Description
Lipid profile

Timepoint
Baseline, 8 and 12 weeks after intervention

Method of measurement
Biochemical analysis

4

Description
Oxidative stress

Timepoint
Baseline, 8 and 12 weeks after intervention

Method of measurement
Biochemical analysis

5

Description
Inflammatory markers

Timepoint
Baseline, 8 and 12 weeks after intervention

Method of measurement
Biochemical analysis

Secondary outcomes

empty

Intervention groups

1

Description
Legumes- control diet including 15% protein, 30% fat and 55% carbohydrate with 1 serving legumes for 8 weeks
Category
Treatment - Other

2

Description
control diet including 15% protein, 30% fat and 55% carbohydrate for 8 weeks
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes clinice of Talaghani Hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Parvin Mirmiran
Street address
No.24, Parveneh St., Yemen Blvd., Chamran Exp.
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Institute for Endocrine Sciences, Shahid Beheshti 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
Department of Clinical Nutrition and Dietetics, Faculty of Nutrition Sciences and Food Technology, N
Full name of responsible person
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Position
Associate professor/PhD
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Person responsible for updating data

Contact
Name of organization / entity
Obesity Research Center, Research Institute for Endocrine Science, Shahid Beheshti University of Med
Full name of responsible person
Somayeh Hosseinpour-Niazi
Position
Other areas of specialty/work
Street address
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Phone
Fax
Email
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