Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effects of Soy nut Supplementation on Glycemic Control, Lipid Profile and Insulin Resistance in Type 2 Diabetic Subjects

Protocol summary

Summary

This study is a prospective and randomized single-blind clinical trial. The aim of this study is effects of soy nut supplementation on glycemic control, lipid profile and insulin resistance in type 2 diabetic subjects. Total of sample size is 70 patient with ages: 30-70 years old. The patients with liver failure, renal failure, heart failure, using insulin, allergy to soy and if patients do not use soy nuts more than five days continuous or ten days discontinuous will be excluded. The patients are randomly divided into two groups. Patients do not know about the protocol of the study. First group receives 60 gram package of Soy nuts without salt, Daily in the morning and the evening for 8 weeks. The second group as a control group does not receive anything. Both groups are matched in terms of taking energy, protein, fat and carbohydrates. Patients basic information such as age and sex, Stature, BMI, serum triglyceride, LDL, HDL, total cholesterol, fasting blood sugar, fasting insulin levels, hemoglobin A1c (HbA1c) will be recorded in both groups before Intervention and after the Intervention period. During the study, both groups are placed under therapeutic life style changes diet and dietary recommendations for diabetes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014022616755N1**
Registration date: **2015-11-14, 1394/08/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-11-14, 1394/08/23

Registrant information

Name
Alireza Sedaghat
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2014-05-10, 1393/02/20

Expected recruitment end date

2014-06-10, 1393/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Soy nut Supplementation on Glycemic Control, Lipid Profile and Insulin Resistance in Type 2 Diabetic Subjects

Public title

Effects of Soy Nut Supplementation on Glycemic Control and Llipid Profile in Diabetic Subjects

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients with type 2 diabetes; Patients with ages: 30-70 years old; BMI less than 35; FBS less

than 250; HbA1c less than 8.5. Exclusion Criteria: Patients with liver failure; Renal failure; Heart failure; Using insulin; Allergy to soy nut.

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: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

To randomization: Consecutive odd and even numbers are assigned to patients. 60 gram package of Soy nuts daily for 8 weeks are administered to odd and even numbered as a control group does not receive anything.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz Jundishapur University Of Medical Sciences

Street address

Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, Golestan BLvd., Ahvaz

City

Ahvaz

Postal code

Approval date

2014-01-04, 1392/10/14

Ethics committee reference number

ajums.REC.1392.258

Health conditions studied

1

Description of health condition studied

Type 2 Diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Fasting blood glucose levels (FBS)

Timepoint

Before intervention and after completion of intervention in the eighth week

Method of measurement

Venous sampling and sent to the laboratory

2

Description

Hemoglobin A1c (HbA1c) levels

Timepoint

Before intervention and after completion of intervention in the eighth week

Method of measurement

Venous sampling and sent to the laboratory

3

Description

The serum levels of triglycerides, LDL, HDL, Total cholesterol

Timepoint

Before intervention and after completion of intervention in the eighth week

Method of measurement

Venous sampling and sent to the laboratory

4

Description

Fasting insulin levels

Timepoint

Before intervention and after completion of intervention in the eighth week

Method of measurement

Venous sampling and sent to the laboratory

5

Description

insulin resistance

Timepoint

Before intervention and after completion of intervention in the eighth week

Method of measurement

By Using the homeostasis model Assessment-insulin resistance (HOMA-ir) formula: fasting glucose (mmol/L) × fasting insulin (μU/ml)/22.5

Secondary outcomes

1

Description

Body mass index (BMI)

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Kg/m2 (Body weight to square of length ratio)

2

Description

Systolic blood pressure

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

mmHg, with manometer in sitting state from right arm

3

Description

Diastolic blood pressure

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

mmHg, with manometer in sitting state from right arm

Intervention groups

1

Description

Group I: Prescription 60 gram package of Soy nuts without salt, Daily in the morning and the evening for 8 weeks.

Category

Other

2

Description

Group II: The second group as a control group does not receive anything.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Fatemeh Heidari

Street address

Golestan Hospital, Farvardin st., Golestan, Ahvaz

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Nader Saki

Street address

Vice chancellor For Research Of Ahvaz Jondishapour University of Medical Sciences, Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd., Ahvaz

City

Ahvaz

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor For Research Of Ahvaz Jundishapur 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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Alireza Sedaghat

Position

fellowship in endocrinology and metabolic diseases

Other areas of specialty/work

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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