

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jul 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3222 2922

##### Email address

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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 Lipid 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**  
Ahvaz

## 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  
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Alireza Sedaghat  
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fellowship in endocrinology and metabolic diseases  
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## Person responsible for scientific inquiries

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**Web page address**

**Person responsible for updating data**

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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*