

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Comparing the effects of substitution of red meat with soybeans and non-soy Legumes on the glycemic control, lipid profile, inflammatory markers and oxidative stress in adults with type 2 diabetes

#### Protocol summary

##### Summary

**Objectives:** The present study is a parallel, randomized trial to compare the effects of substitution of red meat with soybeans and non- soy legumes on the glycemic control, lipid profile, inflammatory markers and oxidative stress in 60 adults with type 2 diabetes for 8 weeks.

**Participants:** Inclusion criteria are type II diabetes for at least 6 months and aged between 40 and 65 years and exclusion criteria are the use of insulin, existence thyroid disorders, gastrointestinal disorders such as bloat, kidney, liver and cardiovascular diseases and a history of allergy to soybeans or legumes.

**Design and setting and conduct:** After obtaining written informed consent of patients, divided into three groups of 20 persons by randomized block design. Intervention: from 4 weeks before intervention in the control group (use of two servings of red meat for three days a week) and two intervention groups (consumption two servings of soy bean and legume for three days a week) use of lipid-lowering drugs be discontinued under medical supervision. Main outcome measures: At the beginning and end of the intervention measurement of height, weight, waist circumference, systolic and diastolic blood pressure, blood glycemic control, lipid profile, inflammatory markers and oxidative stress (By 5 ml fasting blood sample), taking 3-days food record and physical activity will be doing.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015112925276N1**  
Registration date: **2016-04-26, 1395/02/07**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-04-26, 1395/02/07

##### Registrant information

###### Name

Zeinab Hematdar

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 936 594 0281

###### Email address

stud2560183072@sums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Shiraz University of Medical Sciences

##### Expected recruitment start date

2016-01-06, 1394/10/16

##### Expected recruitment end date

2016-03-21, 1395/01/02

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effects of substitution of red meat with soybeans and non- soy Legumes on the glycemic control, lipid profile, inflammatory markers and oxidative stress in adults with type 2 diabetes

##### Public title

the effects of substitution of red meat with soybeans and

non- soy Legumes on diabet improvement

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Having Type II diabetes for at least 6 months/ age between 40 to 65 years/ People with medium and high socio-economic status (with the ability to buy meat, beans or soybeans) Exclusion Criteria: The need to use insulin/ The need to take cholesterol-lowering drugs/ thyroid disorders, gastrointestinal disorders such as bloat, kidney , liver and cardiovascular diseases/ Participate in other studies in the past 6 months/ allergies to soy or bean/ The use of corticosteroids, cyclosporine and warfarin, NSAIDs and immunosuppressive/ Smoking/ Consume Alcohol/ pregnancy or breast-feeding/ history of ovarian cysts

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 60

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

All patients are assigned to one of three groups by blocked randomization: control groups (red meat) and experimental groups (soybeans and legumes) .

## Secondary Ids

### 1

#### Registry name

Shiraz University of Medical Sciences

#### Secondary trial Id

IRCT25276N1

#### Registration date

1394-10-20, 777/01/-1246

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

##### Street address

Zand Street, Medical University Buildings

#### City

Shiraz

#### Postal code

14336 - 71348

#### Approval date

2015-12-31, 1394/10/10

#### Ethics committee reference number

IR.SUMS.REC.1394.144

## Health conditions studied

### 1

#### Description of health condition studied

Non-insulin dependent diabetic patients

#### ICD-10 code

E11

#### ICD-10 code description

Non-insulin-dependent diabetes mellitus

## Primary outcomes

### 1

#### Description

Fasting blood sugar

#### Timepoint

before and after intervention

#### Method of measurement

blood test

## Secondary outcomes

### 1

#### Description

Hb A1C

#### Timepoint

before and after intervention

#### Method of measurement

blood test

### 2

#### Description

Serum insulin

#### Timepoint

before and after intervention

#### Method of measurement

blood test

### 3

#### Description

triglyceride

#### Timepoint

before and after intervention

#### Method of measurement

blood test

## 4

### **Description**

Total cholesterol

### **Timepoint**

before and after intervention

### **Method of measurement**

blood test

## 5

### **Description**

HDL cholesterol

### **Timepoint**

before and after intervention

### **Method of measurement**

blood test

## 6

### **Description**

LDL cholesterol

### **Timepoint**

before and after intervention

### **Method of measurement**

blood test

## 7

### **Description**

Malondialdehyde

### **Timepoint**

before and after intervention

### **Method of measurement**

blood test

## 8

### **Description**

CRP

### **Timepoint**

before and after intervention

### **Method of measurement**

blood test

## 9

### **Description**

blood pressure

### **Timepoint**

Before the intervention, 4 weeks after the intervention, after intervention

### **Method of measurement**

Mercury sphygmomanometer

## 10

### **Description**

weight

### **Timepoint**

Before the intervention, 4 weeks after the intervention, after intervention

### **Method of measurement**

Digital scale

## 11

### **Description**

Waist circumference

### **Timepoint**

Before the intervention, 4 weeks after the intervention, after intervention

### **Method of measurement**

meter

## **Intervention groups**

### 1

#### **Description**

Case 1: Taking a cup of cooked soy beans three days a week and avoiding the use of beans and red meat during the study for 8 weeks

#### **Category**

Treatment - Other

### 2

#### **Description**

Case 2: Taking a cup of cooked beans three days a week and avoiding the use of soy bean and red meat during the study for 8 weeks

#### **Category**

Treatment - Other

### 3

#### **Description**

control: Taking two units of red meat three days a week and avoiding the use of beans and soy beans during the study for 8 weeks

#### **Category**

Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shahid Motahari clinic

##### **Full name of responsible person**

zeinab hematdar

##### **Street address**

Fars, Shiraz, Namazi, Karim Khan Zand Blvd

##### **City**

Shiraz

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Vice chancellor for research of Shiraz University of Medical Sciences

##### **Full name of responsible person**

Doctor Seyyed Basir Hashemi

**Street address**

Medical University of Buildings, Zand Street

**City**

Shiraz

**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 Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

zeinab hematdar

**Position**

MSc student at Shiraz university of medical sciences

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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*