

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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

Madical University of Bildings, 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

Other areas of specialty/work

Street address

Razi Blvd, College of Boulevard secret, Faculty of Nutrition and Food Science

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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