

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of substitution of meat with legumes in the dietary approach to stop hypertension diet on lipid profile, indices of glycemic, inflammation, coagulation, and oxidative stress in patients with type 2 diabetes according to genotype of rs7903146 in the TCF7L2

Protocol summary

Study aim

Effect of substitution of meat with legumes in dietary approach to stop hypertension on lipid profile, indices of glycemic, inflammation, coagulation, and oxidative stress in patients with type 2 diabetes according to genotype of rs7903146 in the TCF7L2

Design

Parallel Randomized Controlled Clinical Trial

Settings and conduct

In this randomized controlled trial, 300 type 2 diabetic patients, whose genotype rs7903146 has been determined and having inclusion criteria, are selected among participants in Tehran Lipid and Glucose Study. Participants will be randomly assigned to one of the following intervention or control groups based on the blocked randomization method. Control group will receive DASH diet with weight reduction and intervention group will receive legume-based DASH diet with weight reduction for 16 weeks. Measurements will be taken at baseline and end of interventions, including laboratory examinations, blood pressure, and anthropometric measurement. In this study neither the main investigator nor the clinical and laboratory assessor will be aware of the patients' treatment assignment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Fasting blood glucose ≥ 126 mg/dl or 2-h plasma glucose ≥ 200 mg/dl treatment with anti-hyperglycemic medications; Aged 35-65 years old; BMI between 25-40 kg/m²; No weight change in past three months; determining transcription factor-7-like 2 rs7903146 genotypes. Non inclusion criteria: Cardiovascular disease; Renal disease; Using anti-inflammatory drugs; Following any specific diet in past three months; Gastrointestinal disease; lower desire to consume legumes; Insulin treatment; Pregnant and lactating women

Intervention groups

Intervention group: Legume-based DASH diet with weight loss
Control group: DASH diet with weight loss

Main outcome variables

Fasting plasma glucose; High sensitivity C reactive protein

General information

Reason for update

Acronym

TLGS

IRCT registration information

IRCT registration number: **IRCT20090203001640N17**
Registration date: **2020-05-20, 1399/02/31**
Registration timing: **prospective**

Last update: **2020-05-20, 1399/02/31**

Update count: **0**

Registration date

2020-05-20, 1399/02/31

Registrant information

Name

Parvin Mirmiran

Name of organization / entity

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

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2500

Email address

mirmiran@endocrine.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-05, 1399/04/15

Expected recruitment end date

2021-01-04, 1399/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of substitution of meat with legumes in the dietary approach to stop hypertension diet on lipid profile, indices of glycemic, inflammation, coagulation, and oxidative stress in patients with type 2 diabetes according to genotype of rs7903146 in the TCF7L2

Public title

Effect of legumes consumption in patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Agreement to participate in the study and completing informed consent form Fasting blood glucose ≥ 126 mg/dl or 2-h plasma glucose ≥ 200 mg/dl or treatment with anti-hyperglycemic medications Aged 35-65 years old Body mass index between 25-40 kg/m² No weight change in past three months determining transcription factor-7-like 2 rs7903146 genotypes

Exclusion criteria:

Cardiovascular disease such as myocardial infarction in past 6 months Renal disease (creatinine $1.4 \geq$ mg/dl for men or ≥ 1.3 mg/dl for women) Alcohol intake, either acute or chronic Using anti inflammatory drugs Following any specific diet in past three months Gastrointestinal disease (e.g. inflammatory bowel diseases) lower desire or lack of desire to consume legumes Insulin treatment Pregnant and lactating women

AgeFrom **30 years** old to **65 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor

Sample sizeTarget sample size: **300****Randomization (investigator's opinion)**

Randomized

Randomization description

Random assignment to intervention and control groups Participants were randomly assigned to intervention or control group in the random blocks based on the random number table. The sequence of permuted blocks was generated with a random number table. An individual

with no clinical involvement in the trial, put the table of intervention or control group in an opaque and sealed envelope based on the random sequence. Then the other person, who was not aware of random sequences and the envelope content, assigned the patients to the intervention or control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is designed as a single blind study. The main investigator and outcome assessor are not aware of each patient's treatment assignment and the main investigator is not involved in the randomization process.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

ethics committee of the Research Institute for Endocrine Sciences, Shahid Beheshti University of Med

Street address

No 24, A'rab St, Yeman Av, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

193954763

Approval date

2020-05-12, 1399/02/23

Ethics committee reference number

IR.SBMU.ENDOCRINE.REC.1399.001

Health conditions studied**1****Description of health condition studied**

Type 2 diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

2**Description of health condition studied**

overweight and obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

Fasting plasma glucose

Timepoint

Before intervention and 16 weeks after intervention

Method of measurement

Enzymatic method

2

Description

high sensitive C reactive protein

Timepoint

Before intervention and 16 weeks after intervention

Method of measurement

ELISA

Secondary outcomes

1

Description

Plasma concentration of total cholesterol

Timepoint

Before intervention and 16 weeks after intervention

Method of measurement

Enzymatic method

2

Description

Plasma concentration of low density lipoprotein cholesterol

Timepoint

Before intervention and 16 weeks after intervention

Method of measurement

Enzymatic method

3

Description

Plasma concentration of high density lipoprotein cholesterol

Timepoint

Before intervention and 16 weeks after intervention

Method of measurement

Enzymatic method

4

Description

Plasma triglyceride concentration

Timepoint

Before intervention and 16 weeks after intervention

Method of measurement

Enzymatic method

5

Description

Tumor necrosis factor alpha concentration

Timepoint

Before intervention and 16 weeks after intervention

Method of measurement

Enzyme-linked immunosorbent assay

6

Description

Interleukin 6

Timepoint

Before intervention and 16 weeks after intervention

Method of measurement

Enzyme-linked immunosorbent assay

7

Description

Fibrinogen concentration

Timepoint

Before intervention and 16 weeks after intervention

Method of measurement

Turbidimeter

8

Description

Plasma catalase activity

Timepoint

Before intervention and 16 weeks after intervention

Method of measurement

Catalase activity assay kit

9

Description

Plasma insulin concentration

Timepoint

Before intervention and 16 weeks after intervention

Method of measurement

Enzyme-linked immunosorbent assay

10

Description

Total antioxidant capacity

Timepoint

Before intervention and 16 weeks after intervention

Method of measurement

Colorimetric

11

Description

Malondialdehyde concentration

Timepoint

Before intervention and 16 weeks after intervention

Method of measurement

Colorimetric

12

Description

Systolic blood pressure

Timepoint

Before intervention and 16 weeks after intervention

Method of measurement

Mercury sphygmomanometers

13

Description

Diastolic blood pressure

Timepoint

Before intervention and 16 weeks after intervention

Method of measurement

Mercury sphygmomanometers

14

Description

weight

Timepoint

Before intervention and 16 weeks after intervention

Method of measurement

Scales

Intervention groups

1

Description

Intervention group: Legume based dietary approach to stop hypertension diet with weight reduction

Category

Treatment - Other

2

Description

Control group: Dietary approach to stop hypertension diet with weight reduction

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran lipid and glucose study unit

Full name of responsible person

Amir-abas Momenan

Street address

No. 320, 30-metri Nirooye Havai

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momenan@endocrine.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Parvin Mirmiran

Street address

No. 24, Aarabi St, Yeman St, Velenjak, Shadid Chamran Highway

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Email

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Somayeh Hosseinpour

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All collected deidentified IPD

When the data will become available and for how long

2 months after publication

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

The data is provided for systematic review at the request of the researcher

From where data/document is obtainable

Data should be requested from Dr. Parvin Mirmiran via mirmiran@endocrine.ac.ir.

What processes are involved for a request to access data/document

The applicant must provide a confirmation letter from the head of the center asking for the data

Comments