# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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 weigh 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 Me

**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 ≥ 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
**Age**
From **30 years** old to **65 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Investigator
- Outcome assessor

**Sample size**
Target 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 lable 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’rabi 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**
Turbiditymeter

### 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**
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## 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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mirmiran@endocrine.ac.ir
**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 scientific inquiries

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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**