Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 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 ḍiet 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)

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