Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jul 2026

effect of substitution of animal proteins with plant proteins in DASH diet on glycemic indicators, lipid profile, Apo lipoproteins, Blood pressure and anthropometric indicators in obese individuals with metabolic syndrome

Protocol summary

Study aim
effect of substitution of animal proteins with plant proteins in DASH diet on glycemic indicators, lipid profile, Apo lipoproteins, Blood pressure and anthropometric indicators in obese individuals with metabolic syndrome

Design
clinical trial with control group with parallel group on 80 patients, double blind, random sequence

Settings and conduct
Eighty patients[intervention group (n = 40)] receive DASH diet containing 2/3 legumes and control group (n = 40) receive DASH diet containing 1/3 legumes refer to the Endocrinology and Metabolism Research Institute See. randomization and assign individuals to two intervention and control groups is hidden for laboratory expert and statistical analysis expert. At the end of the diet plan to reduce weight in patients, 500 kcal of total energy expenditure will be deducted. Biochemical indices and other measurements are assessed at baseline and after 8 weeks of intervention. Nutritional evaluation of individuals is conducted using a 24-hour recall twice a day and 10 ml of blood is taken after 12 hours of fasting.

Participants/Inclusion and exclusion criteria
inclusion criteria: BMI between 25 to 40 kg/m2, age between 30 to 60 years old, not having any specific diet, exclusion criteria: pregnancy , lactation, liver disease (non-alcoholic fatty liver Grade 3), , kidney disease (GFR <60 ml / min / 1.73 m2) and gastrointestinal disease, allergy and use of effective drugs in weight loss

Intervention groups
intervention group: dietary intake of DASH diet containing 2/3 legumes and 1/3 legumes

Main outcome variables
blood glucose

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090203001640N16**
Registration date: **2020-01-13, 1398/10/23**
Registration timing: **prospective**

Last update: **2020-01-13, 1398/10/23**
Update count: **0**

Registration date
2020-01-13, 1398/10/23

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
2020-06-21, 1399/04/01

Expected recruitment end date
2021-06-22, 1400/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
effect of substitution of animal proteins with plant proteins in DASH diet on glycemic indicators, lipid profile, Apo lipoproteins, Blood pressure and anthropometric indicators in obese individuals with metabolic syndrome

Public title
Evaluation of substitution of animal proteins with plant proteins in DASH diet in obese individuals with metabolic syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Agreement to participate in the study and completing informed consent form aged 30-70 years old No change in weight over the past 3 months body mass index: 25-40 having Metabolic syndrome Not having special diet Non-pregnancy and lactation

Exclusion criteria:
Pregnancy and Lactation, having liver disease (non-alcoholic fatty liver Grade 3), kidney disease (GFR <60 ml / min / 1.73 m2), gastrointestinal disease, allergy. Use of effective drugs in weight loss Unwilling to consume legumes and nuts in the diet

Age
From **30 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
This parallel-group randomized clinical trial will be conducted at Research Institute for Endocrine Sciences, SBMU, Tehran, Iran. In this study, patients will be divided into two groups [intervention(DASH diet containing 2/3 plant proteins and 1/3 animal proteins)] and control (DASH diet containing 2/3 animal protein and 1/3 plant proteins) by using random sequence. The allocation ratio will be 1:1. For randomly assignment of patients to the two groups, stratified blocked randomization method will be used.The division of the strata is based on the sexuality so that patients are first classified into men and women groups. After specifying four blocks in different layouts random selection approach will be used to set the allocation of treatment. the allocation of both groups will be concealed from main researcher in the biochemical laboratories and statistician who will analyze the data and the codes that will be placed to the packets will be available to the researchers for random sampling.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is designed as a double blind study. The main researcher and patients are not aware which DASH diet group contains 2/3 plant proteins or 2/3 animal proteins, and the main investigator is not involved in the randomization process

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
ethics committee of national nutrition and food technology research institute

Street address
No. 7, Shahid Farahzadi Blvd, Shahid Hafezi Street (West Arghavan), Qods Town (West), Tehran

City
Tehran

Province
Tehran

Postal code
19395-4741

Approval date
2019-06-19, 1398/03/29

Ethics committee reference number
IR.SBMU.NNFTRI.REC.1398.033

Health conditions studied

1

Description of health condition studied
metabolic syndrome

ICD-10 code
E88.81

ICD-10 code description
metabolic syndrome

2

Description of health condition studied
obesity

ICD-10 code
E66.0

ICD-10 code description
Obesity due to excess calories

Primary outcomes

1

Description
serum concentration of blood glucose
Timepoint
befor the intervention and 8 weeks after intervention
Method of measurement
enzymatic method

Secondary outcomes

1

Description
serum concentration of total cholesterol
Timepoint
before the intervention and 8 weeks after intervention
Method of measurement
enzymatic method

2

Description
serum concentrations of triglyceride
Timepoint
before the intervention and 8 weeks after intervention
Method of measurement
enzymatic method

3

Description
Low density lipoprotein- cholesterol
Timepoint
before the intervention and 8 weeks after intervention
Method of measurement
enzymatic method

4

Description
high density lipoprotein- cholesterol
Timepoint
before the intervention, 8 weeks after intervention
Method of measurement
enzymatic method

5

Description
Serum concentration of Apolipoprotein- A1
Timepoint
before the intervention and 8 weeks after intervention
Method of measurement
enzymatic method

6

Description
Serum concentration of apolipoprotein- B
Timepoint
before the intervention and 8 weeks after intervention
Method of measurement
enzymatic method

7

Description
height
Timepoint
before the intervention and 8 weeks after intervention
Method of measurement
stadiometer

8

Description
weight
Timepoint
before intervention and 8 weeks after intervention
Method of measurement
Seca scale

9

Description
blood pressure
Timepoint
before the intervention and 8 weeks after intervention
Method of measurement
Mercury barometer

10

Description
waist circumference
Timepoint
before the intervention and 8 weeks after intervention
Method of measurement
tape meter

Intervention groups

1

Description
Intervention group: DASH diet including 15% protein, 30% fat and 55% carbohydrate with intake of 2/3 proteins need from plant proteins(contain grains, nuts or seeds and legumes) and 1/3 animal proteins(contain milk, meat, cheese and eggs)
Category
Treatment - Other

2

Description
Control group: DASH diet including 15% protein, 30% fat and 55% carbohydrate with intake of 1/3 proteins need from plant proteins(contain grains, nuts or seeds and legumes) and 2/3 animal proteins(contain milk, meat, cheese and eggs)
Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Taleghani Hospital
Full name of responsible person
Mohammad Hasan Vasei
Street address
Arabi St., Yemen Blvd., Taleghani Hospital., Velenjak
City
Tehran
Province
Tehran
Postal code
19395-4741
Phone
+98 21 2235 7484
Email
Ehsanvasei21@gmail.com

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. 7, West Arghavan Ave., Farahzadi Blvd., Gharb Town,
City
Tehran
Province
Tehran
Postal code
1236549874
Phone
+98 21 2243 9834
Email
Mirmiran@endocrine.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Vice Chancellor for Research, Institute of Nutrition and Food Industry of Iran

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
Mohammad Hasan Vasei
Position
Master Science
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
No.46, Arghavan-E-Gharbi St., Farahzadi Blv., Shahrak-E-Ghods
City
Tehran
Province
Tehran
Postal code
193954741
Phone
+98 21 2235 7484
Email
Ehsanvasei21@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohammad Hasan Vasei
Position
Master Science
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
No 46, Arghavan-E-Gharbi St., Farahzadi Blv., Shahrak-E-Ghods
City
Tehran
Province
Tehran
Postal code
193954741
Phone
+98 21 2235 7484
Email
Ehsanvasei21@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mohammad Hasan Vasei
Position
MSc Student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town,
City
Tehran
Province
Tehran
Postal code
193954741
Phone
+98 21 2235 7484
Email
Ehsanvasei21@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable