Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of dietary approaches to stop hypertension (DASH) diet on metabolic syndrome components and hepatic steatosis indices in subjects with metabolic syndrome

Protocol summary

Study aim

Evaluation of the effect of dietary approaches to stop hypertension (DASH) diet on metabolic syndrome components and hepatic steatosis indices in subjects with metabolic syndrome

Design

Randomized clinical trial

Settings and conduct

This 12-week study is a randomized controlled clinical trial that will investigate the effect of the DASH diet on the components of metabolic syndrome and indices of hepatic steatosis in subjects with metabolic syndrome with metabolic syndrome based on IDF criteria in Yazd city. Participation in the study is completely free and is managed by investigator who explainthe study process, goals, benefits and limitations and obtaining written consent with the participant's signature. Then, by examining other inclusion criteria for entering the study, the subjects are selected to start the intervention. Participants will be divided into intervention group or control group by a computer-generated random numbers table using a stratified randomization process based on gender and age.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 30-60 years old, Diagnosis of metabolic syndrome based on IDF criteria, Sign of informed written consent. Exclusion criteria: 1. Pregnancy and lactation 2. Hereditary hemochromatosis 3. History of gingival or gastroplasty bypass surgery 4. Use of hepatotoxic drugs such as calcium channel blocker and high doses of synthetic estrogens 5. Patients with hypothyroidism 6. Cushing syndrome 7.Kidney failure and kidney stones 8. Cardiovascular disease 9. History of hepatitis B and C 10. Wilson disease

Intervention groups

The intervention group will receive the DASH diet. The control group will receive a standard diet.

Main outcome variables

Components of Metabolic syndrome including Waist circumference (WC); High density lipoprotein-cholesterol (HDL-c); Blood triglycerides (TG); Blood pressure; Fasting plasma glucose (FPG).

General information

Reason for update

We added new secondary outcomes. In addition, we reported actual recruitment start and end dates.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180201038585N12**
Registration date: **2022-10-21, 1401/07/29**
Registration timing: **prospective**

Last update: **2022-12-23, 1401/10/02**
Update count: **1**

Registration date

2022-10-21, 1401/07/29

Registrant information

Name

Karim Parastouei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8248 3516

Email address

parastouei@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-22, 1401/07/30

Expected recruitment end date
2023-01-20, 1401/10/30
Actual recruitment start date
2022-10-22, 1401/07/30
Actual recruitment end date
2022-11-21, 1401/08/30
Trial completion date
empty

Scientific title
The effect of dietary approaches to stop hypertension (DASH) diet on metabolic syndrome components and hepatic steatosis indices in subjects with metabolic syndrome

Public title
The effect of DASH diet in subjects with metabolic syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 30-60 years Diagnosis of Metabolic Syndrome based on IDF criteria Sign of informed written consent
Exclusion criteria:
Pregnancy and lactation Hereditary hemochromatosis History of gingival or gastroplasty bypass surgery Use of hepatotoxic drugs such as calcium channel blocker and high doses of synthetic estrogens Patients with hypothyroidism Cushing syndrome Kidney failure and kidney stone Cardiovascular disease History of hepatitis B and C Wilson disease
Age
From **30 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be divided into intervention group or control group utilizing a random allocation software by a third trained person. A computer-generated random numbers table, presented by Saghaei in 2004, will be used to generate the random sequence. Baseline characteristics of the participants such as gender and age will be determined and recorded before random allocation. Then, using a stratified randomization process based on gender (male/female) and age (30–45 and 45–60 years) the participants will be divided into intervention group or control group. Allocation concealment will be conducted using opaque sealed envelopes to prevent selection bias by concealing the allocation sequence from those assigning participants to the intervention groups.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of baqiayatllah University of Medical Sciences
Street address
Moulla Sadra Ave , Vannak Square
City
Tehran
Province
Tehran
Postal code
1435916471
Approval date
2022-05-21, 1401/02/31
Ethics committee reference number
IR.BMSU.BAQ.REC.1401.016

Health conditions studied

1

Description of health condition studied
Metabolic syndrome
ICD-10 code
E88.81
ICD-10 code description
Metabolic syndrome

Primary outcomes

1

Description
Diastolic Blood Pressure
Timepoint
Before intervention and 12 weeks after the intervention
Method of measurement
Sphygmomanometer

Secondary outcomes

1

Description
Waist Circumference

Timepoint
Before intervention and 12 weeks after the intervention
Method of measurement
Meter

2

Description
Triglyceride
Timepoint
Before intervention and 12 weeks after the intervention
Method of measurement
Enzymatic method

3

Description
High density lipoprotein cholesterol
Timepoint
Before intervention and 12 weeks after the intervention
Method of measurement
Enzymatic method

4

Description
Systolic blood pressure
Timepoint
Before intervention and 12 weeks after the intervention
Method of measurement
Sphygmomanometer

5

Description
Fasting blood glucose
Timepoint
Before intervention and 12 weeks after the intervention
Method of measurement
Enzymatic method

6

Description
Low density lipoprotein cholesterol
Timepoint
Before intervention and 12 weeks after the intervention
Method of measurement
Enzymatic method

7

Description
Total Cholesterol
Timepoint
Before intervention and 12 weeks after the intervention
Method of measurement
Enzymatic method

8

Description
Alanine Aminotransferase
Timepoint
Before intervention and 12 weeks after the intervention
Method of measurement
Enzymatic method

9

Description
Aspartat transaminase
Timepoint
Before intervention and 12 weeks after the intervention
Method of measurement
Enzymatic method

10

Description
Weight
Timepoint
Before intervention and 12 weeks after the intervention
Method of measurement
Scale

11

Description
Body mass index
Timepoint
Before intervention and 12 weeks after the intervention
Method of measurement
Formula

12

Description
Hepatic steatosis index
Timepoint
Before intervention and 12 weeks after the intervention
Method of measurement
Formula

13

Description
Lipid accumulation product
Timepoint
Before intervention and 12 weeks after the intervention
Method of measurement
Formula

14

Description
Visceral adiposity index
Timepoint
Before intervention and 12 weeks after the intervention
Method of measurement
Formula

15

Description
Fatty liver index
Timepoint
Before intervention and 12 weeks after the intervention

Method of measurement
Formula

16

Description
Gamma-glutamyl transpeptidase
Timepoint
Before intervention and 12 weeks after the intervention
Method of measurement
Enzymatic method

17

Description
Atherogenix index of plasma
Timepoint
Before intervention and 12 weeks after the intervention
Method of measurement
Formula

18

Description
Atherogenic coefficient
Timepoint
Before intervention and 12 weeks after the intervention
Method of measurement
Formula

19

Description
Castelli risk index
Timepoint
Before intervention and 12 weeks after the intervention
Method of measurement
Formula

20

Description
Cardiometabolic index
Timepoint
Before intervention and 12 weeks after the intervention
Method of measurement
Formula

21

Description
TyG index
Timepoint
Before intervention and 12 weeks after the intervention
Method of measurement
Formula

22

Description
Metabolic score for insulin resistance
Timepoint
Before intervention and 12 weeks after the intervention
Method of measurement
Formula

Intervention groups

1

Description
Intervention group: The intervention group will receive DASH (Dietary Approaches to Stop Hypertension) diet. This diet contains 52 to 55% carbohydrates, 16 to 18% protein and 30% fat. Calories needed by each patient are estimated based on basal metabolic rate (using the Harris-Benedict equation) and levels of physical activity and energy from food metabolism. 500 kcal for those with a BMI in the range of 25-31 kg/m2 and 700 kcal for those with a BMI more than 31 kg/m2 will be deducted from the total energy required by each person.
Category
Lifestyle

2

Description
Control group: The control group will receive a standard diet. Calories needed by each patient are estimated based on basal metabolic rate (using the Harris-Benedict equation) and levels of physical activity and energy from food metabolism. 500 kcal for those with a BMI in the range of 25-31 kg/m2 and 700 kcal for those with a BMI more than 31 kg/m2 will be deducted from the total energy required by each person.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Yazd Diabetes Center
Full name of responsible person
Mahdieh Hosseinzadeh
Street address
Kashani Ave
City
Yazd
Province
Yazd
Postal code
8915173160
Phone
+98 35 3149 2232
Email
hoseinzade.mahdie@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person
Ali Shiri

Street address
Mollasadra Ave, Vanak Sq, Tehran

City
Tehran

Province
Tehran

Postal code
1435915371

Phone
+98 21 8248 3516

Email
shira.reza@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Karim Parastouei

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Mullasadra Ave, Vannak Sq,Tehran

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1435916471

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parastouei@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Karim Parastouei

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

Contact

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Full name of responsible person
Karim Parastouei

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
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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
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Not applicable