

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 explain the 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 gastropasty 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 gastropasty 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

AgeFrom **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 baqiyatollah University of Medical Sciences

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Moulla Sadra Ave , Vannak Square

City

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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**

Atherogenic 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

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Kashani Ave

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Province

Yazd

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8915173160

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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

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Mollasadra Ave, Vanak Sq, Tehran

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1435915371

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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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Person responsible for scientific inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Karim Parastouei

Position

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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

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Position

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Latest degree

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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