Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effects of DASH (Dietary approach to stop hypertension) diet on severity, frequency, duration of headache and markers of oxidative stress in migraine patients

Protocol summary

Study aim

The effects of DASH (Dietary approach to stop hypertension) diet on severity, frequency, duration of headache and markers of oxidative stress in migraine patients.

Design

Patients will be randomly divided into two groups. Randomization will be done by permuted block randomization method. This study is a two arm parallel group, randomized clinical trial.

Settings and conduct

The study sites of Khorshid and Imam Musa Sadr Clinics are affiliated with Isfahan University of Medical Sciences. The subjects will be randomly divided into two groups of 50 each. The intervention group will receive the DASH diet and the control group will receive the control diet contain healthy dietary advises.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who agree to participate in the study; Diagnosis of migraine by a neurologist according to ICHD-3; Aged between 20 to 50 years old; Body mass index 18.5-30 kg/m2; Exclusion criteria: Men with migraine; Migraine with Aura, Cardiovascular disease, hypertension, Diabetes, Liver disease, Kidney disease, Thyroid disorders, Malignancies and other neurological disorders; Pregnancy and Lactation.

Intervention groups

In this study, 100 people will be included among those with migraine and considering the inclusion and exclusion criteria. For 3 months, the intervention group will receive the DASH diet and the control group will receive the control diet contain healthy dietary advises. DASH diet consist of fruits, vegetables, whole grain and low fat dairy. Control diet includes healthy dietary recommendation based upon dietary pyramid.

Main outcome variables

Migraine Severity Score; Migraine Duration; Migraine Frequency; Headache Impact test; Serum Nitric Oxide; Vitamin C; Serum Glutathione; Total Oxidative Capacity; Total Antioxidant Capacity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121216011763N38**
Registration date: **2019-10-01, 1398/07/09**
Registration timing: **prospective**

Last update: **2019-10-01, 1398/07/09**
Update count: **0**

Registration date

2019-10-01, 1398/07/09

Registrant information

Name
Gholamreza Askari
Name of organization / entity
Isfahan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-21, 1398/08/30

Expected recruitment end date

2020-03-05, 1398/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of DASH (Dietary approach to stop hypertension) diet on severity, frequency, duration of headache and markers of oxidative stress in migraine patients

Public title

Dietary approach to stop hypertension (DASH) diet in migraine

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who agree to participate in the study Diagnosis of migraine by a neurologist according to ICHD-3 Aged between 20 to 50 years old Body mass index between 18.5-30 kg/m2

Exclusion criteria:

Men with migraine Migraine with aura Diagnosis of other disease such as cardiovascular disease, hypertension, diabetes, liver disease, kidney disease, thyroid disorders, malignancies and other neurological problem Pregnancy and lactation

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will conduct based on permuted block randomization method. Each block will have capacity for 4 subjects. Then, within each block, subjects will be randomly assigned to treatment or placebo. Random assignment will be done using a random number table

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 Isfahan University of Medical Sciences

Street address

Hezarjarib street

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2019-09-14, 1398/06/23

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.352

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43.0

ICD-10 code description

Migraine without aura

Primary outcomes

1

Description

Migraine severity

Timepoint

At baseline and after 12 weeks

Method of measurement

Visual analogue scale

2

Description

Migraine frequency

Timepoint

At baseline and after 12 weeks

Method of measurement

Clinical examination

3

Description

Migraine duration

Timepoint

At baseline and after 12 weeks

Method of measurement

Clinical examination

4

Description
Headache impact test
Timepoint
At baseline and after 12 weeks
Method of measurement
HIT questionnaire

5

Description
Serum Nitric Oxide
Timepoint
At baseline and after 12 weeks
Method of measurement
Colorimetric method

6

Description
Serum vitamin C
Timepoint
At baseline and after 12 weeks
Method of measurement
Colorimetric method

7

Description
Total antioxidant capacity
Timepoint
At baseline and after 12 weeks
Method of measurement
Colorimetric method

8

Description
Total oxidant capacity
Timepoint
At baseline and after 12 weeks
Method of measurement
Colorimetric method

9

Description
Serum glutathion
Timepoint
At baseline and after 12 weeks
Method of measurement
Colorimetric method

Secondary outcomes

1

Description
Blood pressure
Timepoint
At baseline and after 12 weeks
Method of measurement
Sphygmomonometer

2

Description
Weight
Timepoint
At baseline and after 12 weeks
Method of measurement
Digital scale

Intervention groups

1

Description
Intervention group: Intervention group will receive DASH diet for 3 months. DASH diet have been designed to be included high levels of fruits, vegetables, whole grains and low fat dairy. In order to examine the adherence of participants to diet, serum levels of vitamin C have been assessed. Also, all of the assessment have been conducted at baseline and end of study
Category
Treatment - Other

2

Description
Control group: The control group will receive a 3-month control diet including healthy dietary advice. Healthy dietary recommendation includes healthy advises based on food guide pyramid.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Khorshid Clinic
Full name of responsible person
Gholamreza Askari
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2

Recruitment center
Name of recruitment center

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
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Position
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Person responsible for updating data

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Province

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Postal code

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Phone

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Fax

Email

arman4369@gmail.com

Web page address

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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

Major part of information will be available for population.

When the data will become available and for how long

12 months after publication

To whom data/document is available

Available for people working in academic institutions

Under which criteria data/document could be used

To conduct similar studies

From where data/document is obtainable

En

What processes are involved for a request to access data/document

The data will send as soon as possible, after receiving the request.

Comments