

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Effect of Iranian traditional medicine-based diet on monthly bouts of headache in Migraineurs

Protocol summary

Summary

The aim of research is the study of Effects of forbidding Flatulent and Vaporizer Foods On Migraine. Method of research is before and after interventional study, conducted in a sample size of 49 patients with migraine. Inclusion criteria are 1.all men or women patients were in the range age of 18 to 60 years old, 2.patients that their Migraine headache is confirmed by the neurologist. Exclusion criteria are: 1.patient's unwillingness to continue to participate in the research, 2.detect any incidence of systemic diseases. The intervention is to avoid eating some foods for four weeks. Food ban, contains a list of flatulent and Vaporizer foods that as a list is available to patients. At the beginning of the four-week monitoring period, then at the beginning of the intervention and at the end of the fourth week intervention, patients visit by researcher and study in terms severity, duration, frequency of headaches, quality of life and nutritional status by questionnaires that will be evaluated. The findings will be compared before and after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016120331210N1**

Registration date: **2017-02-13, 1395/11/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-13, 1395/11/25

Registrant information

Name

Majid Soltanpour Gharibdousti

Name of organization / entity

Medicine Faculty of Shahed University

Country

Iran (Islamic Republic of)

Phone

+98 21 5121 4055

Email address

dr.m.soltanpour@gmail.com

Recruitment status

Recruitment complete

Funding source

Shahed University

Expected recruitment start date

2016-11-28, 1395/09/08

Expected recruitment end date

2017-02-26, 1395/12/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Iranian traditional medicine-based diet on monthly bouts of headache in Migraineurs

Public title

Food Avoidance of Migraine

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria in the study: a man or woman age 18 to 60 years; confirm the presence of migraine according to the ICHD-III respected by neurologist; No other Neurological diseases and systemic diseases such as diabetes, hypertension, liver failure, renal failure; Non-pregnant patient. Exclusion criteria: patient's unwillingness to continue to participate in the research, planning to get pregnant or to carry a pregnancy test

positive; detect any incidence of systemic diseases including liver disease, renal, cardiac and neurological diseases than any migraines during the study; Establish non-compliance with the prohibition of food intake according to criteria.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **49**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medicine Faculty of Shahed University

Street address

Opposite of Imam Khomeiny Shrine

City

Tehran

Postal code

Approval date

2016-11-27, 1395/09/07

Ethics committee reference number

Shahed.REC.1395.134

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes

1

Description

Frequency of headaches

Timepoint

Before intervention, One month after intervention initiation

Method of measurement

According to patients notes

2

Description

Duration of headaches

Timepoint

Before intervention, One month after intervention initiation

Method of measurement

According to patients notes

3

Description

Severity of headaches

Timepoint

Before intervention, One month after intervention initiation

Method of measurement

Visual Analogue Scale

4

Description

Analgesic use

Timepoint

Before intervention, One month after intervention initiation

Method of measurement

According to patients notes

Secondary outcomes

1

Description

Midas score

Timepoint

Before intervention, one month after intervention initiation

Method of measurement

Questionnaire

Intervention groups

1

Description

Avoid of eating some foods for four weeks. Food ban, Contains a list of flatulent and Vaporizer foods that as a list is available to patients.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahed Traditional Iranian Medicine Salamatgah
Full name of responsible person
Majid Soltanpour Gharibdousti
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Tim Health care, Third Dashtestan Ave, Shariati Ave.
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahed University of Medical Sciences
Full name of responsible person
Elham Emaratkar
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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

Shahed University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty
Analytic Code
empty
Data Dictionary
empty