Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of therapeutic efficacy of apple-quince syrup formulation compared to placebo in the treatment of patients with migraine headache: a double-blind randomized clinical trial

Protocol summary

Summary

The purpose of this study is to assess the therapeutic efficacy of apple-quince syrup compared to placebo in patients with migraine headache. A neurologist selects patients from those who are aged from 18 to 60 years and are considered to be affected by by migraine according to the International Classification of Headache Disorders (ICHD) criteria, the third edition. Subsequently, 62 patients are selected and randomly divided into two treatment groups. One group keeps an apple-quince syrup diet and the other group keeps a placebo diet in which 15 ml syrup is consumed, three times in a day after each meal for 4 weeks. Patients are evaluated before and four weeks after treatment . Two groups are evaluated finally in terms of the number of headaches per month, headache intensity and the duration of headache, according to the pain self-efficacy score. The history of diabetes, hypertension and addiction are important exclusion criteria. The random allocation of patients to intervention and control group will be based on the block randomization method.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016071929002N1**
Registration date: **2016-09-26, 1395/07/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-09-26, 1395/07/05

Registrant information

Name
Ahmad Karimi
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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of therapeutic efficacy of apple-quince syrup formulation compared to placebo in the treatment of patients with migraine headache: a double-blind randomized clinical trial

Public title

Evaluating the effect of apple-quince syrup on migraine headache

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Confirming the existence of migraine according to the International Classification of Headache Disorders (ICHD), the third edition, by a neurologist; Aged 18 to 60 years. Exclusion Criteria: History of unknown abdominal pain, History of acute abdomen surgery, History of renal and hepatic disease, History of obstructive gastrointestinal disease, History of malignancy, Existence of warning signs such as GI bleeding, Weight loss and anemia, Diabetes mellitus (fasting blood sugar test above 110 mg/dl), HTN, Addiction to opioids and stimulants, Alcohol consumption, Patients who do not want to continue the research, Patients who are non-compliant with taking the prescribed drug, Unpredictable complications leading to drug intolerance such as idiosyncratic complications, Using medical or traditional laxatives and any significant change in lifestyle affecting headache of the patient during intervention.

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: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

The random allocation of patients to intervention and control group will be based on the block randomization method.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Next to the Ayatollah Taleghani Hospital, Martyr Arabi Street, Yemen Street, Martyr Chamran Highway

City

Tehran

Postal code

Approval date

2016-07-03, 1395/04/13

Ethics committee reference number

IR.SBMU.REC.1395.1

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes

1

Description

Headache Severity

Timepoint

The Form of "Evaluation of the Severity, Duration and Frequency of Migraine Headaches" is delivered to each patient. During the four weeks prior to the intervention, each patient completes the form. Then the drug or placebo is given to the patient for 4 weeks as the treatment while the form is being completed. Also, during 4 weeks after the intervention, information is recorded. So, the Form is completed in three phases (4 weeks before intervention, during treatment and 4 weeks after intervention) by the patient. Pain intensity for each patient is determined and recorded by Visual Analogue Scale (VAS) criteria.

Method of measurement

visual scale of ten

2

Description

Headache Frequency

Timepoint

The Form of "Evaluation of the Severity, Duration and Frequency of Migraine Headaches" is delivered to each patient. During the four weeks prior to the intervention, each patient completes the form. Then the drug or placebo is given to the patient for 4 weeks as the treatment while the form is being completed. Also, during 4 weeks after the intervention, information is recorded. So, the Form is completed in three phases (4 weeks before intervention, during treatment and 4 weeks after intervention) by the patient.

Method of measurement

Recording the headache frequency in the questionnaire

3

Description

Headache Duration

Timepoint

The Form of "Evaluation of the Severity, Duration and Frequency of Migraine Headaches" is delivered to each

patient. During the four weeks prior to the intervention, each patient completes the form. Then the drug or placebo is given to the patient for 4 weeks as the treatment while the form is being completed. Also, during 4 weeks after the intervention, information is recorded. So, the Form is completed in three phases (4 weeks before intervention, during treatment and 4 weeks after intervention) by the patient

Method of measurement

Recording the headache duration by patient in the questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: Apple-quince syrup, 15 ml three times daily after meals for 4 weeks. Patients will be evaluated at the baseline and 4 weeks after starting intervention in terms of headache severity, headache frequency and headache duration. To make apple-quince syrup, equal volumes of apple and quince juice will be mixed and boiled until get it thick (one-seventh of the initial volume).

Category

Placebo

2

Description

Placebo Group: Placebo syrup, 15 ml three times daily after meals for 4 weeks. Patients will be evaluated at the baseline and 4 weeks after starting intervention in terms of headache severity, headache frequency and headache duration. To make placebo, sugar, glycerin and water will be mixed and boiled until get it thick.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialized Center for Headache of Bagheiyatallah Azam Hospital

Full name of responsible person

Ahmad Karimi

Street address

Sheikh Bahaie intersection, Molla Sadra street

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Somaye Esmaili

Street address

No. 8, Shams Alley, Opposite Tavanir, Valiasr Street

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Shahid Beheshti 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

Name of organization / entity

School of Traditional Medicine, Shahid Beheshti University of Medical Sciences

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Ahmad Karimi

Position

Ph.D Student of Traditional Medicine

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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