

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 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

##### Name of organization / entity

School of Traditional Medicine, Shahid Beheshti  
University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4441 2314

##### Email address

drkarimiahmad@sbmu.ac.ir

##### 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

Tehran

## 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

##### Full name of responsible person

Ahmad Karimi

##### Position

Ph.D Student of Traditional Medicine

##### Other areas of specialty/work

##### Street address

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

##### City

Tehran

##### Postal code

##### Phone

+98 21 8877 2521

##### Fax

##### Email

drkarimiahmad@sbmu.ac.ir

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

School of Traditional Medicine, Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mina Movahhed

**Position**

Assistant professor

**Other areas of specialty/work****Street address**

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

**City**

Tehran

**Postal code****Phone**

+98 21 8877 2521

**Fax****Email**

m\_movahhed@sbmu.ac.ir

**Web page address****Street address**

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

**City**

Tehran

**Postal code****Phone**

+98 21 8877 2521

**Fax****Email**

drkarimiahmad@sbmu.ac.ir

**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*

**Person responsible for updating data****Contact****Name of organization / entity**

School of Traditional Medicine, Shahid Beheshti  
University of Medical Sciences

**Full name of responsible person**

Ahmad Karimi

**Position**

Ph.D. Student of Traditional Medicine

**Other areas of specialty/work**