

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Investigation of efficacy of ginger consumption in migraine prophylaxis in patient with migraine

#### Protocol summary

##### Study aim

Determining the Effect of Ginger on Preventive Migraine Treatment in Migraine Patients

##### Design

This study is a clinical trial with control group, parallel groups, double blind, randomized, phase 3, on 108 patients with migraine.

##### Settings and conduct

patients are divided into two groups (intervention and placebo) to receive medication, and migraine profiles will be assessed at the beginning, end of the first month, and at the end of the intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria included people 18 to 50 years of age, with a history of migraines with or without aura according to the International Headache Association (IHS) criteria at least one year after diagnosis, moderate to severe migraine (It is defined as: number of headache attacks 2-15 times in a month, attacks with lesser intensity and duration that cause one's disability and disruption in their daily routine).

##### Intervention groups

Intervention: Daily two ginger pills (500 mg of ginger powder) for 3 months control: Two placebo tablets (500 mg of starch) daily for 3 months

##### Main outcome variables

The efficacy of treatment is evaluated based on the frequency of migraine headaches per month, changes in MIDAS score, headache length and severity.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200126046263N1**

Registration date: **2020-02-18, 1398/11/29**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-02-18, 1398/11/29**

Update count: **0**

##### Registration date

2020-02-18, 1398/11/29

##### Registrant information

###### Name

Foroogh Anjiri zadeh

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3337 8721

###### Email address

foroogh\_anjirizadeh@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-02-04, 1398/11/15

##### Expected recruitment end date

2020-03-19, 1398/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigation of efficacy of ginger consumption in migraine prophylaxis in patient with migraine

##### Public title

Investigation of efficacy of ginger consumption in migraine prophylaxis in patient with migraine

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

18 to 50 years Migraine history with or without migraine is according to the International Headache Association (IHS) standard, which is at least one year after diagnosis. Diagnosis of mild to severe migraine (defined as the number of headache attacks 2 to 15 times a month, or less frequent and severe attacks that cause a person's disability and disruption in their daily routine).

**Exclusion criteria:**

Non-migraine headaches Allergy to ginger Other neurological diseases (stroke, Alzheimer's, etc.) taking anticoagulants Pregnant and lactating women

**Age**

From **18 years** old to **50 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **108**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The total number of specimens randomly assigned by the process will be divided into two groups by random random blocks and each group will consist of 54 persons. The blocking method will be used for randomization. To do this, a random allocation sequence will be created through the reputable website <https://www.sealedenvelope.com/simple-randomiser/v1/lists>.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

This study is a double blind clinical trial (participant, researcher). Ginger and placebo supplements will be packaged in similar boxes, and the researcher and patients will not be informed of the contents of the packs until the end of the study.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

**Street address**

Ahvaz Jundishapur University of Medical Sciences

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

15794-61357

**Approval date**

2019-12-28, 1398/10/07

**Ethics committee reference number**

IR.AJUMS.REC.1398.738

**Health conditions studied**

**1**

**Description of health condition studied**

migraine

**ICD-10 code**

G43

**ICD-10 code description**

Migraine

**Primary outcomes**

**1**

**Description**

headache

**Timepoint**

Measurement at baseline (Before the Intervention) and at the end of first and third months after supplementation

**Method of measurement**

MIDAS

**Secondary outcomes**

**1**

**Description**

Intensity and frequency

**Timepoint**

Measurement at baseline (Before the Intervention) and at the end of first and third months after supplementation

**Method of measurement**

questionnaire

**Intervention groups**

**1**

**Description**

Intervention group: Two 500 mg ginger tablets daily for 3 month

**Category**

Treatment - Other

## 2

### Description

Control group: Two 500 mg placebo tablets daily (containing drug starch) for 3 months

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Golestan hospital

##### Full name of responsible person

Forough Anjiri Zadeh

##### Street address

Golestan Boulevard Golestan Hospital Neurology Department

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

15794-61357

##### Phone

+98 61 3337 8721

##### Email

foroogh\_anjirizadeh@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Dr Mohammad Badvi

##### Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Ave.

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

15794-61357

##### Phone

+98 61 3336 2414

##### Email

itc@ajums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

##### Full name of responsible person

Forooh Anjiri Zadeh

##### Position

Master student

##### Latest degree

Master

##### Other areas of specialty/work

Nutrition

##### Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Ave.

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

15794-61357

##### Phone

+98 61 3337 8721

##### Email

foroogh\_anjirizadeh@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Bijan Helli

##### Position

Assistant Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nutrition

##### Street address

Department of Nutrition, Faculty of Paramedical Sciences, Ahvaz Jundishapur University of Medical Sciences, Golestan Ave.

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

15794-61357

##### Phone

+98 61 3337 8721

**Email**

helli-b@ajums.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Forough Anjiri Zadeh

**Position**

Master of nutrition science

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

**Street address**

Department of Nutrition, Faculty of Paramedical Sciences, Ahvaz Jundishapur University of Medical Sciences, Golestan Ave.

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

15794-61357

**Phone**

+98 61 3337 8721

**Email**

foroogh\_anjirizadeh@yahoo.com

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

-

**When the data will become available and for how long**

-

**To whom data/document is available**

-

**Under which criteria data/document could be used**

-

**From where data/document is obtainable**

-

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

-

**Comments**