Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

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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

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Khouzestan

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
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Sponsors / Funding sources

1

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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
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
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Person responsible for updating data

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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