# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Determination of the therapeutic efficacy of ginger in the treatment of migraine headaches

### Protocol summary

**Study aim**
Effect of Ginger capsules on Pain Reduction in Patients with Migraine Headaches Purpose

**Design**
This clinical trial randomized with software; single blind in which 80 patient with Migraine headache with inclusion criteria divided into two groups of intervention and control

**Settings and conduct**
This study is performed on referrer to private offices and clinics in Shahrekord in single blind. the patient chooses one of the two drugs randomly and the name of each person and the code of the drug provided to him by the secretary is registered and neither the patient nor the doctor has any information about the type of medication. And only when analyzing the data will the names of each individual and his drug be identified to complete the information profile of the patients by mentioning the name of the drug received by them. In that tester, they do not know the type of drug received.The intervention group, in addition to routine treatments, receive ginger powder. The control group receives placebo in addition to routine treatments orally.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: age 18 to 65 years; history of migraine headache before the study based on IHS criteria; headache from moderate to severe less than six days by visual analogue scale(Vas) score; having no disease such as renal failure, liver disease, heart disease, active stomach ulcer, and diabetes.

**Intervention groups**
The treatment group receives two ginger capsules of 250 along with 500 mg/day Depakene orally. The control group receives 500 mg/day Depakene alone daily that is their routine therapy .

**Main outcome variables**
The severity of headache; the number of headaches per month; sleep quality

### General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20220818055740N2**
Registration date: **2022-09-27, 1401/07/05**
Registration timing: **retrospective**

Last update: **2022-09-27, 1401/07/05**
Update count: **0**

**Registration date**
2022-09-27, 1401/07/05

**Registrant information**
**Name**
Nahid Jivad
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2019-06-29, 1398/04/08
**Expected recruitment end date**
2019-09-01, 1398/06/10
**Actual recruitment start date**
2019-06-29, 1398/04/08
**Actual recruitment end date**
2019-09-01, 1398/06/10
**Trial completion date**
empty

**Scientific title**

Determination of the therapeutic efficacy of ginger in the treatment of migraine headaches

**Public title**
Determination of the therapeutic efficacy of ginger in the treatment of migraine headaches
**Purpose**
Diagnostic
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Inclusion criteria: Age between 18 to 65 years; history of migraine headache before performing the study based on IHS criteria; headache from moderate to severe less than six days by visual analogue score(Vas); absence of diseases such as liver, heart, active stomach ulcer, diabetes and renal failure.
**Exclusion criteria:**
Exclusion criteria: Abnormal vital signs during the study;, new abnormal findings during CT scan; dissatisfaction patients to continue the study;, and observation of drug sensitivity.
**Age**
From **18 years** old to **65 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Care provider

**Sample size**
Target sample size: **80**
Actual sample size reached: **80**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
The random allocation of the participants to the intervention and control groups will be done using random allocation software. Then, many envelopes will be prepared according to the number of participants in the study. Then, number 1 will be recorded on the first envelope, number 2 on the second envelope, and etc. The sequence of assignment of the participants will be determined by the software and each assignment will be put inside each envelope respectively. At the time of study , the specified envelope for each individual will be opened and the individual will be assigned to one of the intervention and control groups according to the option recorded inside the envelope.
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
The single blindness of the study was performed in this process that at first the mentioned drugs received code without any labels and the patient selected one of the two drugs randomly. Then, the name of each person and the drug code provided to him registered by the secretary. Neither the patient nor the doctor was not aware of the type of medication. The name of each person and his drug was specified only during analyzing the data, and completed the patients' information profile by mentioning the name of the drug received by them.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Shahrekord University of Medical Sciences
**Street address**
Kashani Blvd, Shahrekord University of Medical Sciences, Shahrekord, Iran
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Chahar-Mahal-va-Bakhtiari
**Postal code**
8818718791
**Approval date**
2019-08-23, 1398/06/01
**Ethics committee reference number**
IR.SKUMS.REC.1398.018

## Health conditions studied

### 1

**Description of health condition studied**
Migraine
**ICD-10 code**
G43
**ICD-10 code description**
Migraine

## Primary outcomes

### 1

**Description**
Migraine headache
**Timepoint**
One month after intervention
**Method of measurement**
VAS, PSQI, MIDAS questionnaires

## Secondary outcomes

### 1

**Description**
Migraine headache

**Timepoint**
One month after intervention
**Method of measurement**
VAS, PSQI, MIDAS questionnaires

## Intervention groups

### 1

**Description**
The control group received 500 mg/day Depakene orally daily once for sixteen weeks mgmanufactured by Zintoma (Gol darou Co.)
**Category**
Diagnosis

### 2

**Description**
Intervention group: The treatment group received two ginger capsules 250mg along with 500 mg/day Depakene manufactured by Zintoma (Gol darou Co.) orally for sixteen weeks.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Kashani Hospital of Shahrekord
**Full name of responsible person**
Nahid Jivad
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## Sponsors / Funding sources

### 1

**Sponsor**
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**Full name of responsible person**
Esfandiar Heydarian
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heydarian.e@skums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Shahre-kord 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**
Shahre-kord University of Medical Sciences
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**Position**
Specialist
**Latest degree**
Specialist
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available
**Justification/reason for indecision/not sharing IPD**
There is no further information
**Study Protocol**
No - There is not a plan to make this available
**Statistical Analysis Plan**
No - There is not a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
No - There is not a plan to make this available
**Analytic Code**
No - There is not a plan to make this available
**Data Dictionary**
No - There is not a plan to make this available