

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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)

Phone

+98 38 3335 1031

Email address

jivad@skums.ac.ir

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		by mentioning the name of the drug received by them.	
Public title	Determination of the therapeutic efficacy of ginger in the treatment of migraine headaches	Placebo	Not used
Purpose	Diagnostic	Assignment	Parallel
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.	Other design features	
Age	From 18 years old to 65 years old	Secondary Ids	empty
Gender	Both	Ethics committees	
Phase	3	1	
Groups that have been masked	- Participant - Care provider	Ethics committee	
Sample size	Target sample size: 80 Actual sample size reached: 80	Name of ethics committee	Ethics committee of Shahrekord University of Medical Sciences
Randomization (investigator's opinion)	Randomized	Street address	Kashani Blvd, Shahrekord University of Medical Sciences, Shahrekord, Iran
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.	City	Shahrekord
Blinding (investigator's opinion)	Single blinded	Province	Chahar-Mahal-va-Bakhtiari
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	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 manufactured 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

Street address

Kashani Hospital, Shahrekord University of Medical Sciences, Parastar Avenue, Shahrekord

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Province

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

Esfandiar Heydarian

Street address

Shahrekord University of Medical Sciences, Vice

Chancellor of Research and Technology, Kashani Blvd, Shahrekord

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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

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

Full name of responsible person

Nahid Jivad

Position

Specialist

Latest degree

Specialist

Other areas of specialty/work

Neurology

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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