

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Investigating the effectiveness and non-effectiveness of Ravand herbal capsule and Placebo on migraine headaches

Protocol summary

Study aim

Investigating the effectiveness of Ravand herbal capsule and placebo on migraine headaches

Design

This is a double-blinded clinical trial. A total of 64 patients with migraine headaches that are eligible for inclusion in the study will be selected conveniently and randomly will be assigned to intervention and control groups. Each participant will be assigned a code.

Settings and conduct

This study will be conducted as double-blind in project collaborator's office (Dr. Darius Afshari). In such a way that the main investigator and the participants in the study do not know that they are in the intervention group or in the control group

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having more than 3 attacks per month in the last three months; Having more than 3 attacks at the base time; Migraine beginning at least one year before entering the plan; The onset of migraine before the age of 50
Exclusion criteria: Chronic tension headaches or other headaches for more than 15 days per month; Pregnancy, breastfeeding; Patients do not dependent on alcohol or other illegal substances

Intervention groups

The intervention group, in addition to the routine drug, will receive 1 of 720 mg capsule per day, prepared by Bo Ali drug company, for three months at night before bedtime with hot water. The control group, in addition to routine drug, will receive 1 of 720 mg placebo capsule per day for three nights before bedtime with hot water.

Main outcome variables

Headache severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150824023742N1**

Registration date: **2017-12-26, 1396/10/05**

Registration timing: **prospective**

Last update: **2017-12-26, 1396/10/05**

Update count: **0**

Registration date

2017-12-26, 1396/10/05

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3826 2052

Email address

mrezaei@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-05, 1396/10/15

Expected recruitment end date

2018-04-09, 1397/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness and non-effectiveness of Ravand herbal capsule and Placebo on migraine headaches

Public title

Investigating the effectiveness of Ravand herbal capsule

on migraine headaches

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Having more than 3 attacks per month in the last three months
Having more than 3 attacks at the base time
Migraine beginning at least one year before entering the plan
The onset of migraine before the age of 50
Exclusion criteria:
Chronic tension headaches or other headaches for more than 15 days per month
Pregnancy, breastfeeding
Patients do not dependent on alcohol or other illegal substances

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization method will be performed with 4 blocks. One of the project partners carries out the randomization plan and writes codes for people on a sheet and this sheet remains with him or her until the end of the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
Researcher and participants have been blinded to this study. There is no information about assigning people to groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

بلوار شهید بهشتی، ساختمان شماره 2، دانشگاه علوم پزشکی، معاونت تحقیقات و فناوری

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Approval date
2017-11-05, 1396/08/14

Ethics committee reference number
kums.rec.1396.434

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G98

ICD-10 code description

Nervous system disorder NOS

Primary outcomes

1

Description

Headache severity

Timepoint

At the beginning of the study, one month after the beginning of the study and the end of the study

Method of measurement

Base on Migraine Disability Assessment (MIDAS) and Headache Impact Test(HIT6)

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group, in addition to the routine drug, will receive 1 of 720 mg capsule per day, prepared by Bo Ali drug company, for three months at night before bedtime with hot water

Category

Treatment - Drugs

2

Description

The control group, in addition to routine drug, will receive 1 of 720 mg placebo capsule per day for three nights before bedtime with hot water.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Afshari's office

Full name of responsible person

Dr. Daryoush Afshari

Street address

Shariati Ave. Dr. Afshari's office

City

Kermanshah

Province

Kermanshah

Postal code

6719851351

Phone

+98 83 3727 8025

Email

afshari_d@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3836 0014

Email

fnajafi@kums.ac.ir

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, Kermanshah 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**

Kermanshah University of Medical Sciences

Full name of responsible person

Negin Fakhri

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Biostatistics

Street address

Isar Square, Dolatabad Blvd, School of Public Health

City

Kermanshah

Province

Kermanshah

Postal code

6719851351

Phone

+98 83 3826 4447

Email

n.fakhri@yahoo.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Mansour rezaei

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Biostatistics

Street address

Isar Square, Dolatabad Blvd, School of Public Health

City

Kermanshah

Province

Kermanshah

Postal code

6719851351

Phone

+98 83 3826 4447

Fax**Email**

mrezaei@kums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Negin Fakhri

Position

MSc student

Latest degree

Bachelor

Other areas of specialty/work

Biostatistics

Street address

Isar Square, Dolatabad Blvd, School of Public Health

City

Kermanshah

Province

Kermanshah

Postal code

6719851351

Phone

+98 83 3826 4447

Email

n.fakhri@yahoo.com

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

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Not applicable

Title and more details about the data/document

En The main outcomes of the study will be shared.

When the data will become available and for how long

4months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Researchers who have a similar study and found contradictory results that are not logical

From where data/document is obtainable

En To receive the documentation, email send for update manager

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

En In a10-day period, the documents will be sent e-mail

Comments