Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 begining 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

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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

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Isar Square, Dolatabad Blvd, School of Public Health

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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

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Person responsible for updating data

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MSc student
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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