

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

A comparative survey of the Sodium valproate and Sodae herbal capsule effects on migraine pain

Protocol summary

Study aim

Comparison of the effect of sodium valproate and sodae capsule on migraine headaches

Design

This study is a double-blind clinical trial. 90 patients with primary migraine included in the study by convenience method will be randomly assigned to either intervention or control groups. Each participant will be assigned a code.

Settings and conduct

This study will be conducted in a clinic and in the personal office of the project partner (Dr. Daryoush Afshari and Dr. Masoud Ghiasian). The researcher and study participants will not aware 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, Start migraines at least one year before entering the project, Start migraines before age 50. Exclusion criteria: Chronic tension headaches or other headaches for more than 15 days a month, Pregnancy and lactation, Patients should not be addicted to alcohol or other illegal substances.

Intervention groups

The intervention group will take one 720 mg sodae capsule made by Boo Ali Daroo Company, with warm water every night before going to bed for three months. The control group will take one 720 mg Sodium Valproate with warm water every night before going to bed for three months.

Main outcome variables

Severity of migraine headache

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200126046272N3**

Registration date: **2020-09-27, 1399/07/06**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-27, 1399/07/06**

Update count: **0**

Registration date

2020-09-27, 1399/07/06

Registrant information

Name

Negin Fakhri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3826 2005

Email address

n.fakhri94@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative survey of the Sodium valproate and Sodae herbal capsule effects on migraine pain

Public title

Comparison of the Sodium valproate and Sodae herbal

capsule effects on migraine pain

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
 Start migraines at least one year before entering the project
 Start migraines before age 50
Exclusion criteria:
 Chronic tension headaches or other headaches for more than 15 days a month
 Pregnancy, lactation
 Patients should not be addicted to 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: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
The block randomization method will be performed with 4 blocks. A colleague will be done a randomization plan and write the code for people, and it remains with the project colleague until the end of the study. First, a list of blocks will be prepared and one number will be assigned to each block, then random numbers will be generated from 1 to 6, and according to these random numbers, the corresponding block will be used, and the list of random allocation of intervention and control will be determined.

Blinding (investigator's opinion)
Double blinded

Blinding description
The researcher and the participants in this study were kept blind. They have no information about the assignment of individuals to groups.

Placebo
Not 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

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

City

Kermanshah

Province

Kermanshah

Postal code

6719851351

Approval date

2020-09-12, 1399/06/22

Ethics committee reference number

IR.KUMS.REC.1399.614

Health conditions studied

1

Description of health condition studied

migraine

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes

1

Description

severity of migraine

Timepoint

Baseline, Three months after the Baseline

Method of measurement

Based on Headache Disability Scale (MIDAS) and
Headache Severity Test (HIT6)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will take one
720 mg sodae capsule made by Boo Ali Daroo Company,
with warm water every night before going to bed for
three months

Category

Treatment - Drugs

2

Description

Control group: The control group will take one 720 mg
Sodium Valproate with warm water every night before
going to bed for three months.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital Clinic

Full name of responsible person

Dr Daryoush Afshari

Street address

Bostan Clinic, Imam Reza Hospital, Bagh Abrisham

City

Kermanshah

Province

Kermanshah

Postal code

6719851351

Phone

+98 83 3826 2005

Email

afshari_d@yahoo.com

2

Recruitment center

Name of recruitment center

Sina hospital clinic

Full name of responsible person

Dr Masoud Ghiasian

Street address
Hamedan - Mirzadeh Eshghi I St. - Honarsestan St. -
Farshchian Hospital
City

Hamedan

Province

Hamadan

Postal code

6516848741

Phone

+98 81 3838 1740

Email

masoud_ghiasian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Booali Daroo pharmaceutical company

Full name of responsible person

Alireza Masoumi

Street address

No. 49, No. 6 Alley, Twenty-meter Angle, Azar Street

City

Qom

Province

Isfahan

Postal code

7935637149

Phone

+98 25 3720 9544

Email

amasumi24@gmail.com

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Booali Daroo pharmaceutical company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin
Type of organization providing the funding

Industry

2

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr Farid Najafi

Street address
Vice chancellor for research and technology, Building
2, University of Medical Sciences, shahid Beheshti
Boulevard
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?

No

Title of funding source

Booali Daroo pharmaceutical company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin
Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Negin Fakhri

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Biostatistics

Street address

Student Research Committee , School of Public Health, Shahid Bahonar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6719851351

Phone

+98 83 3826 4447

Email

n.fakhri94@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Mansour Rezaei

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Biostatistics

Street address

School of Public Health, Dolatabad Boulevard, Isar Square

City

Kermanshah

Province

Kermanshah

Postal code

6719851351

Phone

+98 83 3826 4447

Email

mrezaei@kums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Negin Fakhri

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Biostatistics

Street address

Student Research Committee , School of Public Health, Shahid Bahonar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6719851351

Phone

+98 83 3826 4447

Email

n.fakhri94@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

The main implications will be shared after the study is completed.

When the data will become available and for how long

4 month

To whom data/document is available

Upon request, the study results will be made available to other academic researchers.

Under which criteria data/document could be used

People who have the same study and come up with contradictory results that are not rational.

From where data/document is obtainable

Send email updates for documentation.

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

Documentation will be emailed within a 10-day timeframe.

Comments