

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### A comparative survey of the Sodium valproate and Sodae herbal capsule side effects in migraine patients

#### Protocol summary

##### Study aim

Comparison of the side effects of "sodium valproate and sodae capsule" on migraine patients

##### 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 1 720 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 1 720 mg Sodium Valproate with warm water every night before going to bed for three months.

##### Main outcome variables

Drug side effects

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200126046272N2**

Registration date: **2020-05-14, 1399/02/25**

Registration timing: **prospective**

Last update: **2020-05-14, 1399/02/25**

Update count: **0**

##### Registration date

2020-05-14, 1399/02/25

##### 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 side effects in migraine patients

##### Public title

Comparison of the Sodium valproate and Sodae herbal capsule side effects in migraine patients

## 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

2020-03-03, 1398/12/13

## Ethics committee reference number

IR.KUMS.REC.1398.1190

## Health conditions studied

### 1

#### Description of health condition studied

Migraine

#### ICD-10 code

G98.8

#### ICD-10 code description

Other disorders of nervous system

## Primary outcomes

### 1

#### Description

side effects

#### Timepoint

Baseline, Three months after the Baseline

#### Method of measurement

Record the side effects that the patient reports, Laboratory tests of people's blood samples

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The intervention group will take 1 720 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

The control group will take 1 720 mg Sodium Valproate with warm water every night before going to bed for three months.

#### Category

Treatment - Drugs

## 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**

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?**

Yes

**Title of funding source**

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**

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**

Mansoue 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

+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****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**