# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

13 Jul 2026

## Comparison of the effect of sodium valproate and Levetiracetam on the prevention of migraine headaches

### Protocol summary

**Study aim**
Comparison of the effect of sodium valproate and Levetiracetam on the prevention of migraine headaches on patients referred to Emam Ali Clinics of Shahrekord in 1397.

**Design**
A clinical trial without a parallel control group, single-blind, randomized

**Settings and conduct**
After considering the entry and exit criteria, 80 migraine patients referred to Imam Ali Shahrekord clinic were randomly assigned to one of two groups: sodium valproate or Levetiracetam. Patients were allowed to take 500 mg of acetaminophen if they had mild and severe pain and lasted for 8 hours. The routine treatment for both groups was 80 mg/day of propranolol.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Age 18 to 65 years old; Migraine headache history for at least 6 months before study based on IHS criteria; Moderate to the severe headache for less than 6 days with Visual Analogue Scale; Natural Signs and Natural Nerve Findings; Exclusion criteria: Patients with kidney failure, liver disease, heart disease, active stomach ulcer disease or diabetes or abnormal vital symptoms; Allergy to valproate and Levetiracetam; Pregnant or lactating women; Cases of other types of headaches such as sinus headaches; Taking nonsteroidal anti-inflammatory drugs within 24 hours or valproate over the past 2 weeks

**Intervention groups**
Patients are divided into two intervention groups. One of the two groups is sodium valproate and the other group is receiving Levetiracetam

**Main outcome variables**
Headache severity; Number of headaches per month

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20171030037093N14**
Registration date: **2019-07-02, 1398/04/11**
Registration timing: **prospective**

Last update: **2019-07-02, 1398/04/11**
Update count: **0**

**Registration date**
2019-07-02, 1398/04/11

**Registrant information**

**Name**
Sadra Ansaripour

**Name of organization / entity**
Shahrekord University of Medical Sciences

**Country**
Iran (Islamic Republic of)

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+98 31 3650 3487

**Email address**
st_ansari.s@skums.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2019-07-23, 1398/05/01

**Expected recruitment end date**
2019-10-23, 1398/08/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Comparison of the effect of sodium valproate and Levetiracetam on the prevention of migraine headaches

**Public title**
Evaluation of the effect of sodium valproate and Levetiracetam on the prevention of migraine headaches
**Purpose**
Diagnostic
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Age 18 to 65 years old Migraine headache history for at least 6 months before study based on IHS criteria Moderate to severe headache for less than 6 days with Visual Analogue Scale Natural Signs and Natural Nerve Findings.
**Exclusion criteria:**
Patients with kidney failure, liver disease, heart disease, active stomach ulcer disease or diabetes or abnormal vital symptoms Allergy to valproate and Levetiracetam Pregnant or lactating women Cases of other types of headaches such as sinus headaches Taking nonsteroidal anti-inflammatory drugs within 24 hours or valproate over the past 2 weeks
**Age**
From **18 years** old to **65 years** old
**Gender**
Both

**Phase**
2
**Groups that have been masked**

- Participant

**Sample size**
Target sample size: **80**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Patients are randomly assigned to one of the two groups by selecting the cards named A and B.
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
The drugs were coded without any tags, and the patient randomly selected one of two drugs by choosing the code, and the name of each individual and the prescription drug code was recorded by the clerk. The patient did not have any type of drug
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Shahrekord University of Medical Sciences
**Street address**
Vice chancellor for research, Building No. 2, University headquarters, Ayatollah Kashani Blvd
**City**
Shahrekord
**Province**
Chahar-Mahal-va-Bakhtiari
**Postal code**
8815713492
**Approval date**
2018-07-22, 1397/04/31
**Ethics committee reference number**
IR.SKUMS.REC.1397.138

## Health conditions studied

### 1

**Description of health condition studied**
migraine
**ICD-10 code**
G43
**ICD-10 code description**
Migraine

## Primary outcomes

### 1

**Description**
Headache severity
**Timepoint**
Before the start of the study, notes were taken every 30 days
**Method of measurement**
Based on VAS and doctor

### 2

**Description**
Number of headaches per month
**Timepoint**
Before the start of the study, notes were taken every 30 days
**Method of measurement**
MIDAS questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: The first group received 500 mg of levetiracetam per day
**Category**
Treatment - Drugs

**2**

**Description**
Intervention group: The second group received 500 mg/day sodium sulfate.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Imam Ali Clinic
**Full name of responsible person**
Narges Maleki
**Street address**
Shariati Blvd., Imam Ali Clinic
**City**
Shahrekord
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Chahar-Mahal-va-Bakhtiari
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8816788640
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Dr.safari@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shahre-kord University of Medical Sciences
**Full name of responsible person**
Dr. seyed Kamal Solati(Associate Professor of Psychology)
**Street address**
Vice chancellor for research, Building No. 2, University headquarters, Ayatollah Kashani Blvd
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**Email**
kamal_solati@yahoo.com
**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**
Mohammadhosein Saffari
**Position**
Assistant Professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Neurology
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Latest degree**
Specialist

**Other areas of specialty/work**
Neurology

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**Postal code**
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**Phone**
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**Email**
Dr.safari@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be 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**
Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**
No - There is not a plan to make this available

**Analytic Code**
Yes - There is a plan to make this available

**Data Dictionary**
Yes - There is a plan to make this available

**Title and more details about the data/document**
Information about the main outcome can be shared.

**When the data will become available and for how long**
Start the access period 4 months after publishing the results

**To whom data/document is available**
Researchers working in academia

**Under which criteria data/document could be used**
Use data to complete clinical trial studies

**From where data/document is obtainable**
Imam Ali Hospital

**What processes are involved for a request to access data/document**
After the investigation of researcher request and presentation of required documents will

**Comments**