

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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 Ansari pour

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+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

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Shahrekord

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Chahar-Mahal-va-Bakhtiari

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8816788640

Phone

+98 38 3224 2696

Email

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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+98 38 3334 2414

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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Position

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Latest degree

Specialist

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Latest degree

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Email

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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