

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Comparative study of the clinical effect and side effects of lacosamide and sodium valproate in reducing and controlling seizures in generalized seizures during six months

Protocol summary

Study aim

Comparative study of the clinical effect and side effects of lacosamide and sodium valproate in reducing and controlling seizures in generalized seizures during six months

Design

This study is an unblinded clinical trial method. 120 eligible patients are randomly assigned to two intervention groups. The first group is treated with lacosamide and the second group is treated with sodium valproate, and the patients are examined for the number of seizures and brain scans and side effects.

Settings and conduct

Patients referred to Shahid Beheshti Hospital of Qom with generalized tonic clonic seizures are divided into two groups using block randomization method. The first group is treated with lacosamide with a dose of 200 mg twice a day, and the second group is treated with sodium valproate 500 mg twice a day, and the patients of both groups are treated daily before the start of treatment and three months after the start. The treatment and six months after the start of the treatment are checked in terms of reduction or complete control of seizure attacks and brain scan findings (in terms of presence of seizure waves) and drug side effects.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Seizures in general tonic clonic; over eighteen years of age; consent to participate in the study; Not taking multiple anticonvulsants at the same time Exclusion criteria: Patients' willingness to withdraw from the study; any condition that makes follow-up of patients impossible; Having a chronic disease that impairs the patient's evaluation; suffering from heart diseases; pregnancy

Intervention groups

In the intervention group, lacosamide is administered orally at a dose of 200 mg twice a day, and in the control

group, sodium valproate is administered orally at a dose of 500 mg twice a day.

Main outcome variables

Control of generalized seizures.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220524054982N1**

Registration date: **2022-11-06, 1401/08/15**

Registration timing: **prospective**

Last update: **2022-11-06, 1401/08/15**

Update count: **0**

Registration date

2022-11-06, 1401/08/15

Registrant information

Name

Payam Molavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3322 2023

Email address

molavi.payam@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-06-05, 1402/03/15

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty
Scientific title
Comparative study of the clinical effect and side effects of lacosamide and sodium valproate in reducing and controlling seizures in generalized seizures during six months

Public title
Investigation of the effectiveness of lacosamide in generalized seizures.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having generalized tonic-clonic seizures Over eighteen years of age Consent to participate in the study Not taking multiple anticonvulsants at the same time

Exclusion criteria:

Willingness of patients to withdraw from the study - Having a chronic disease that interferes with the evaluation of the patient Having heart diseases pregnancy

Age
From **18 years** old to **85 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization will be done (blocks 4 and 6). Proprietary sequences and secret codes are generated using www.sealedenvelope.com.

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo

Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee

Qom University of Medical Sciences and Health Services

Street address

Qom Province, Qom, Shahid Lavasani St, MV2R+P89

City

Qom

Province

Ghous

Postal code

3736175513

Approval date

2022-03-06, 1400/12/15

Ethics committee reference number

IR.MUQ.REC.1401.004

Health conditions studied

1

Description of health condition studied

Generalized tonic-clonic seizures.

ICD-10 code

G40

ICD-10 code description

Epilepsy and recurrent seizures

Primary outcomes

1

Description

tonic-clonic seizure

Timepoint

On the first day and three months later and six months after starting the drug

Method of measurement

EEG device and patient bedside

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, lacosamide is used orally and monotherapy at a dose of 200 mg twice a day (any brand). Patients are followed up for six months and checked for the number of seizures.

Category

Treatment - Drugs

2

Description

In the control group, the drug sodium valproate with a dose of 500 mg twice a day is used orally and monotherapy. Patients are followed up for six months and checked for the number of seizures.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital, Qom

Full name of responsible person

Seyyed Amir Hejazi

Street address

Qom, Shahid Beheshti Boulevard, Azadegan Square,
Shahid Beheshti Hospital

City

Qom

Province

Ghous

Postal code

3719964797

Phone

+98 912 306 2043

Email

assh.hejazi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Alireza Koohpaei

Street address

No. 83, Safashehr St., Shahid Lotfi Niaser- Shahid Lotfi
Niaser Alley, Safashehr Street, Qom

City

Qom

Province

Ghous

Postal code

93456-37169

Phone

+98 912 252 2066

Email

koohpaei19@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ghous 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

Ghous University of Medical Sciences

Full name of responsible person

Seyyed Amir Hejazi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

Street address

Qom, Shahid Beheshti Boulevard, Azadegan Square,
Shahid Beheshti Hospital

City

QOM

Province

Ghous

Postal code

3719964797

Phone

+98 25 3612 2000

Email

assh.hejazi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Payam Molavi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurology

Street address

Qom, Shahid Beheshti Boulevard, Azadegan Square,
Shahid Beheshti Hospital

City

Qom

Province

Ghous

Postal code

3719964797

Phone

+98 25 3612 2000

Email

Molavi.payam@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Payam Molavi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurology

Street address

Qom, Shahid Beheshti Boulevard, Azadegan Square,
Shahid Beheshti Hospital

City

Qom

Province

Ghoum

Postal code

3719964797

Phone

+98 25 3612 2000

Email

Molavi.payam@yahoo.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

In this study, statistical data (mean, minimum and maximum) of demographic variables of all samples and not individually studied can be published and the results of drug effectiveness after data analysis can be published without mentioning the names and details of individuals

When the data will become available and for how long

Start the access period after publishing the results

To whom data/document is available

All scientific and academic researchers with mentioning the name and scientific affiliation

Under which criteria data/document could be used

Using the method of studying and analyzing data and results with the permission of the authors or scientific citations in journals, articles and sources is allowed.

From where data/document is obtainable

To the corresponding author whose email details were given and also specified in the relevant articles

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

The request will be sent by email. After consulting with the other authors and agreeing to sponsor the project, the information that can be published will be made available to another person or organization

Comments