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 colonic 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

Ghoum

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
Ghoum
Postal code
3719964797
Phone
+98 912 306 2043
Email
assh.hejazi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ghoum 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
Ghoum
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
Ghoum 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
Ghoum 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
Ghoum
Postal code
3719964797
Phone
+98 25 3612 2000
Email
assh.hejazi@gmail.com

Person responsible for scientific inquiries

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

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