Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation and comparison of the effect of lacosamide with levetiracetam for control of resistant partial onset epilepsy

Protocol summary

Study aim
Determining and comparing the effect of lacosamide and levetiracetam to control resistant partial onset epilepsy attacks

Design
Clinical trial with control group, with parallel groups, without blinding, randomized, phase 3 on 60 patients. With the help of random allocation software, the order of random allocation of patients to two groups is determined.

Settings and conduct
This study is performed in the clinic of Al-Zahra and Kashani hospitals. Lacosamide is added to the first group and Levetiracetam is added to the second group. According to different shape and color of two drugs, it is not possible to blind doctor and patient. Data was presented to analyzer as code A and codeB, meanwhile analyzer was unaware of how patients were divided into groups. Patients will be examined for the frequency of attacks and side effects of drugs and EEG changes in the first, second and third months.

Participants/Inclusion and exclusion criteria
Inclusion criteria : patients with resistant partial onset epilepsy, written informed consent, age more than 18 years Exclusion criteria: cardiac arrhythmias for lacosamide group, pregnancy for lacosamide group, renal failure for levetiracetam group, mood disorders for levetiracetam group

Intervention groups
The first intervention group is resistant partial onset epilepsy receiving lacosamide from Actoverco Company. Lacosamide is started orally at a dose of 50 mg twice daily and is increased to 300 mg daily depending on the patient's response and tolerance. Lacosamide is used for 3 months. The second intervention group recieve levetiracetam from Cobel Darou Company. Levetiracetam is started at a dose of 500 mg twice daily orally and can be increased to 3000 mg daily. Levetiracetam is used for three months.

Main outcome variables
frequency of resistant partial onset epilepsy ;abnormal changes in the electroencephalogram; Drug side effects

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210925052579N1**
Registration date: **2022-03-18, 1400/12/27**
Registration timing: **prospective**

Last update: **2022-03-18, 1400/12/27**
Update count: **0**

Registration date
2022-03-18, 1400/12/27

Registrant information
Name
Maryam Sadat hosseini darenjani
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 71 4459 9283
Email address
dr.maryam.hosseini9896@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-03-19, 1400/12/28
Expected recruitment end date
2022-07-21, 1401/04/30
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of the effect of lacosamide with levetiracetam for control of resistant partial onset epilepsy

Public title

Lacosamide and levetiracetam in partial epilepsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with resistant partial onset epilepsy written informed consent age more than 18 years

Exclusion criteria:

cardiac arrhythmias for lacosamide group pregnancy for lacosamide group renal failure for levetiracetam group mood disorders for levetiracetam group

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Information of all patients was given to random allocation software. The software categorized the patients into two groups by simple randomization method individually and in such a way that the mean age in the two groups was almost the same (with a difference of less than one standard deviation).

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

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences and Health Services, Hezar Jerib St

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2021-08-01, 1400/05/10

Ethics committee reference number

IR.MUI.MED.REC.1400.352

Health conditions studied

1

Description of health condition studied

drug Resistant partial epilepsy

ICD-10 code

G40.01

ICD-10 code description

Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable

Primary outcomes

1

Description

frequency of seizures in resistant partial onset epilepsy

Timepoint

Three months before the intervention, 1, 2 and 3 months after taking the drug

Method of measurement

questionnaire

2

Description

abnormal changes in the electroencephalogram

Timepoint

before the intervention and 3 months after taking drugs

Method of measurement

taking electroencephalogram

Secondary outcomes

1

Description

Drug side effects after taking lacosamide and levetiracetam

Timepoint

Within three months after starting the drug

Method of measurement

questionnaire

Intervention groups

1

Description
The first intervention group is resistant partial onset epilepsy receiving lacosamide . Lacosamide is started orally at a dose of 50 mg twice daily and is increased to 300 mg daily depending on the patient's response and tolerance.Lacosamide is used under the brand name LACSA made by ACTOVERCO company and patients are treated with lacosamide for 3 months.

Category
Treatment - Drugs

2

Description
The second intervention group is resistant partial onset epilepsy receiving levetiracetam. Levetiracetam is started at a dose of 500 mg twice daily orally and can be increased to 3000 mg daily. Levetiracetam is used with the Levebel brand made by COBELDAROU company. Patients receive levetiracetam for three months.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra hospital
Full name of responsible person
Dr. Mohammad Reza Najafi
Street address
Al-Zahra Hospital, Sofe Blvd
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
najafi@med.mui.ac.ir

2

Recruitment center
Name of recruitment center
Ayatollah Kashani hospital
Full name of responsible person
Dr. Mohammad Reza Najafi
Street address
Ayatollah Kashani hospital, Kashani St
City
Isfahan
Province
Isfehan
Postal code
8183983434
Phone
+98 31 3620 2020
Email
najafi@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Mansour Siavash Dastjerdi
Street address
Building No. 4, Isfahan University of Medical Sciences and Health Services, Hezar Jerib St
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 8138
Email
siavash@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Maryam Sadat Hosseini Darenjani
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Neuroscience
Street address

No 360, Alley 3/6, Bagh hose Blvd

City
Shiraz

Province
Fars

Postal code
7175967489

Phone
+98 71 4459 9283

Email
dr.maryam.hosseini9896@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dr. Mohammad Reza Najafi

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Neuroscience

Street address
Al-Zahra Hospital, Sofe Blvd

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3620 2020

Email
najafi@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dr. Mohammad Reza Najafi

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Neuroscience

Street address
Al-Zahra Hospital, Sofe Blvd

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3620 2020

Email
najafi@med.mui.ac.ir

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
Data on the main outcome of resistant partial onset epilepsy with lacosamide and levetiracetam can be generally shared.

When the data will become available and for how long
Six months after publishing the results.

To whom data/document is available
Everyone has access

Under which criteria data/document could be used
Available for systematic review and meta-analysis.

From where data/document is obtainable
First Author and author colleagues.(Via email)

What processes are involved for a request to access data/document
By email to the first author of the article and colleagues

Comments