

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 receive 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

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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

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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

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2

Recruitment center

Name of recruitment center

Ayatollah Kashani hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Mansour Siavash Dastjerdi

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Building No. 4, Isfahan University of Medical Sciences and Health Services, Hezar Jerib St

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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

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

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Name of organization / entity

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Position

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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