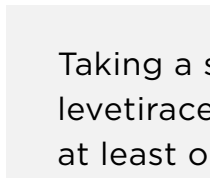
ESLICARBAZEPINE ACETATE (ESL)

Eslicarbazepine Acetate (ESL) as an Add-On Therapy In Partial Onset Seizures

What is This Study About?

This study is looking at how effective and safe eslicarbazepine acetate is in people ≥ 18 years old with focal or partial-onset seizures, when it's added to their current anti-seizure medication(s).

Seizures will be recorded in seizure diaries and by the wearable seizure detection device. This device will be given to participants to use during the study.



There will be two ways that people can participate in this study.

Who Can Participate?

18+ ≥ 18 years old

ESL Has **NEVER** taken ESL before

Diagnosis of epilepsy with the one or more of the following seizure types:

- simple partial-onset (focal) seizures with motor symptoms
- complex partial-onset (focal) seizures with impaired awareness
- partial-onset (focal) seizures that go into generalized seizures

Has had at least 3 focal-onset (partial) seizures in the last 6 months

Participants will be assigned to one of the two study arms or groups:

Taking a stable dose of levetiracetam or lamotrigine for at least one month before screening, with no history of adjunctive (or add-on) treatment

OR

Taking a stable dose of 1 or 2 anti-seizure drugs (except oxcarbazepine)

How Can I Participate

The study is 31 weeks in duration

Up to 10 site visits and 3 telephone visits

The following may be checked in each study visit:

- ECG or EKG
- Physical Examination
- Blood Tests
- Nervous System Assessments

Study will end with a 4-week safety follow up

Are There Risks?

People with Asian ancestry may carry a genetic marker (called allele HLA-B*1502), which may put them at increased risk of serious dermatologic reactions (e.g., Stevens-Johnson Syndrome).

The treatment may not improve a person's seizures.

The dosing plans and safety checks that are designed to protect participants are detailed in a protocol that was designed by researchers and doctors and reviewed by an Institutional Review Board (IRB

If the participant is unable to tolerate treatment with ESL, the study team will help them to taper off the medication slowly where possible, unless abrupt discontinuation is necessary.

EPILEPSY FOUNDATION

For more information, visit

https://clinicalconnection.com/clinical-trials-from-other-databases/study-location-selection/431534

After completion of this study, the study drug is commercially available and may be covered by insurance providers, and Medicare and Medicaid. Subjects will need to confirm with their individual insurance provider if they are covered under the terms of their policy with their provider. Sunovion Pharmaceuticals Inc.® offers a Patient Assistance Program to help to help subjects who are eligible to get help paying for their prescription.