



Study Title: XEN1101 as Adjunctive Therapy in Focal-onset Epilepsy, with an Open-Label Extension (X-TOLE)

“Do you have adult focal-onset epilepsy with frequent seizures despite your current medication?”

What is this study about?

This study is looking at whether taking the investigational medication XEN1101 reduces the number of seizures a person has when they have focal-onset epilepsy. In this study, XEN1101 (a potassium channel modulator) would be given in addition to your current anti-seizure medication(s).

Who can participate?

To be part of this study, people must:

- Be 18-75 years of age
- Have been diagnosed with focal epilepsy at least 2 years ago
- Be on treatment with a stable dose of 1 to 3 anti-seizure medications for at least 30 days before participating in the study
- Be able to keep accurate seizure diaries

People can't be part of this study if they have a history of:

- Primary generalized seizures (have seizures that affect both sides of the brain)
- Clusters of seizures within the past 12 months, where individual seizures could not be accurately counted
- Status epilepticus in the past 12 months

How can I participate?

- Interested people will be screened to confirm if they are eligible to join the study.
- If you are eligible for this study, there will be a baseline period of 8 weeks to look at how often your seizures happen on your current anti-seizure medicines.
- You will then be treated with the addition of either the study medication XEN1101 at three possible doses or a placebo medication for 8 weeks. (A placebo is a treatment or therapy with no expected therapeutic benefit.) Neither you, your doctor nor the investigator will know which group you are in. This is called double-blind randomization.
- During the screening, baseline, and treatment periods you will attend scheduled in-person visits with the study doctor to review your seizure diary and to have several tests. These tests may include physical or neurological examination, vital signs, ECG (electrocardiogram – a non-invasive test that looks at heart rhythm) and other laboratory or blood tests.



- After completing the 8-week treatment period, you will have the option to enter the open label extension phase of the study where you are guaranteed to receive the study medication for up to one year. You can also choose not to proceed and instead finish your participation at that point.
- Two follow-up visits after the treatment or extensions phase will finish your participation in the study.

Are there risks?

- With all trial drugs and devices, there is the chance the treatment may not help a person's seizures.
- Possible side effects are sleepiness or drowsiness, dizziness or lightheadedness, and blurry vision or headaches.
- Study staff will review the known risks in detail with you before you decide whether or not to participate.

For more information, visit: <https://www.xtolestudy.com>.