

XEN 1101

- Xen 1101 works in a new way and has shown very high effectiveness in studies so far.
- This is the last, large study, a phase 3, double-blind, randomized clinical trial to study the effects of Xen 1101 on seizures in patients with focal epilepsy that is not completely controlled with other drugs.
- Adults with focal epilepsy 18 to 75 years of age are eligible.
- The safety, efficacy and tolerability will be studied.
- Patients who complete the study may be eligible for an open-label extension trial.
- Total duration is about 6 months.

DARIGABAT

- Benzodiazepines (drugs such as valium) are often used for seizure treatment, but have side effects such as sleepiness. Darigabat is a benzodiazepine but avoids many of these side effects.
- This is a double-blind, placebo-controlled trial with an open label extension to assess the safety and efficacy of CVL-865 in individuals with drug-resistant focal onset seizures.
- Patients with epilepsy with focal seizures between 18-75 years old are eligible.
- Safety, tolerability, and efficacy of the tablets will be studied.
- Total duration is about 6 months.

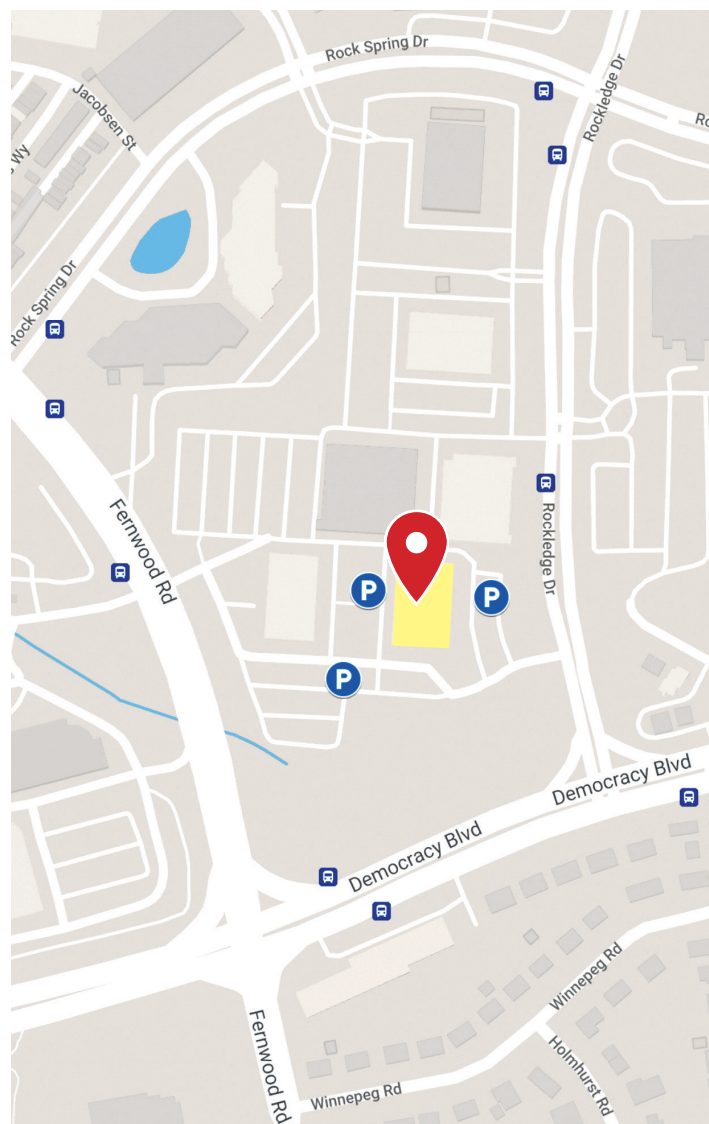


THE MID-ATLANTIC EPILEPSY AND SLEEP CENTER

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CLINICAL TRIALS IN EPILEPSY

See if you qualify

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There are several new treatments for epilepsy in development. They can often help patients whose seizures are not completely controlled with their drugs. Learn more below about epilepsy clinical trials at our center.

Clinical trials are performed for patients to gain access to new medications that can provide better seizure coverage with less side effects. All medications are approved by the FDA before they can be available to patients. In order for new medications to be approved by the FDA and available for use, clinical trials are needed before a medication becomes publicly available. These trials are all developed together with the FDA.

TSC 1 or 2 patients may be eligible for the following clinical trials at our center. If you are interested, please contact us to see whether there may be a good study for you. Travel reimbursement and compensation will be provided.

GANAXOLONE

- Ganaxolone has a unique way of targeting the GABA_A receptor pathway that may be affected in TSC, and prior studies showed reduction in seizures in TSC patients.
- This is a phase 3, double-blind, randomized clinical trial to study the effects of ganaxolone on epilepsy in TSC.
- Patients with TSC between 1 to 65 years of age, and with epilepsy refractory to ≥ 2 antiseizure medications are eligible.
- The study duration is about 20 weeks.

- After the trial, there is an open-label extension, during which patients may receive the treatment at no cost.

CENOAMATE

- Cenobamate has been an exceptionally effective medication for adults with epilepsy. It has led to seizure freedom in over 20% of patients. It is now being studied for use in children.
- This is an open label safety and efficacy phase 3 study with open-label extension, where patients can receive the medication after the trial ends, if desired.
- Children with partial onset seizures aged 2-17 years old are eligible.
- Safety and tolerability will be studied.
- Total duration is about 6 months, followed by open-label extension.

STACCATO ALPRAZOLAM

- Prolonged seizures or seizure clusters require rapid, effective treatments that can be given easily by a caregiver. This medication (also known as Xanax, which has been used since the 1970's) will be delivered through a new device where patients breathe in the medication, similar to asthma inhalers. This causes the medication to act very fast compared to other rescue medications.
- This is an open-label study in patients with prolonged seizures or clusters of seizures.
- Every participant will receive a single dose of the medication (no seizures required) to study how the medication is absorbed.

JNJ 40411813

- Several antiseizure medications are often used to control seizures in an individual and levetiracetam is a commonly used medication. The new drug JNJ 40411813 added to levetiracetam increases the response to levetiracetam by 25 times. This trial will study the effects of the drug on seizures in patients treated with levetiracetam or other anti-epileptic drugs.
- This is a double-blind, randomized clinical trial.
- Adults with focal onset seizures 18 to 69 years of age are eligible.
- The safety, efficacy and tolerability will be studied.
- The trial duration is about 22 weeks.