

shine EPILEPSY

PHASE 2/3 CLINICAL TRIAL



ABOUT EPILEPSY

Epilepsy is a chronic brain disorder that affects people of all ages and causes recurring, unprovoked seizures.¹

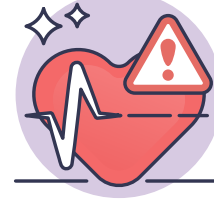
APPROXIMATELY **1.5 MILLION PEOPLE IN THE US AND 50 MILLION WORLDWIDE** HAVE EPILEPSY.^{1,2}



Epilepsy is one of the most **common neurological diseases** globally.¹



People with epilepsy tend to have **more physical problems and higher rates of anxiety and depression**.¹



The risk of **premature death** in people with epilepsy is up to **three times higher** than for the general population.¹

ABOUT SEIZURES

Seizures are sudden surges of abnormal and excessive electrical activity in your brain and can affect how you appear or act. Where and how the seizure presents itself can have profound effects.³

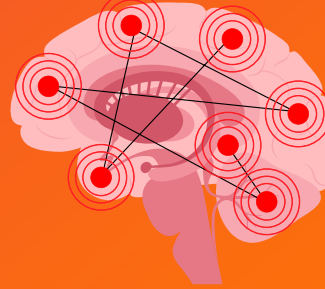
There are **two main types of seizures** that describe where a seizure starts in the brain and how it may affect a person:⁴

Focal Seizures



Focal seizures affect up to approximately **61% of people with epilepsy**.⁵ They begin on **one side of the brain** and may cause changes in awareness, behavior, sensation, or abnormal movements usually on just one side of the body.⁴

Generalized Seizures



Generalized seizures begin on **both sides of the brain** at the same time and usually cause a loss of consciousness or awareness and may also cause abnormal movements on both sides of the body.⁴

UNMET NEED FOR NEW EPILEPSY TREATMENT OPTIONS

There is a high unmet need for new epilepsy treatment options with **fewer adverse events**.⁵



Approximately **40% of people with epilepsy are drug-resistant**.⁵



There is an urgent need for more research, better treatments, and more support for people with epilepsy.⁵

SHINE CLINICAL TRIAL OVERVIEW

The Shine Clinical Trial is a national multi-site, randomized, double-blind placebo-controlled Phase 2/3 study to evaluate the efficacy, safety and tolerability of BHV-7000 in patients with idiopathic generalized epilepsy.

Participants are enrolled in the study for at least seven months with six visits including a 30-day screening phase, a 24-week double treatment phase, an optional open-label extension phase of at least one year, and a post-dosing follow-up safety visit.*

MONTH 1	MONTH 2	MONTH 3	MONTH 4	MONTH 5	MONTH 6	MONTH 7
30 DAYS	24 WEEKS					
ELIGIBLE PARTICIPANTS WILL BE REQUIRED TO TAKE BHV-7000 OR PLACEBO ONCE DAILY.						

* If a study participant continues to have seizures during the study, they will not have to stay in the study for 24 weeks but will exit the study and have the option of going to the open label phase early.



The primary objective of the study is to compare the efficacy of BHV-7000 to placebo as adjunctive therapy for subjects with idiopathic generalized epilepsy with generalized tonic-clonic (GTC) seizures as measured by the time to the second day with a GTC seizure during the double-blind phase.

KEY ELIGIBILITY CRITERIA

Between the ages of 18 to 75

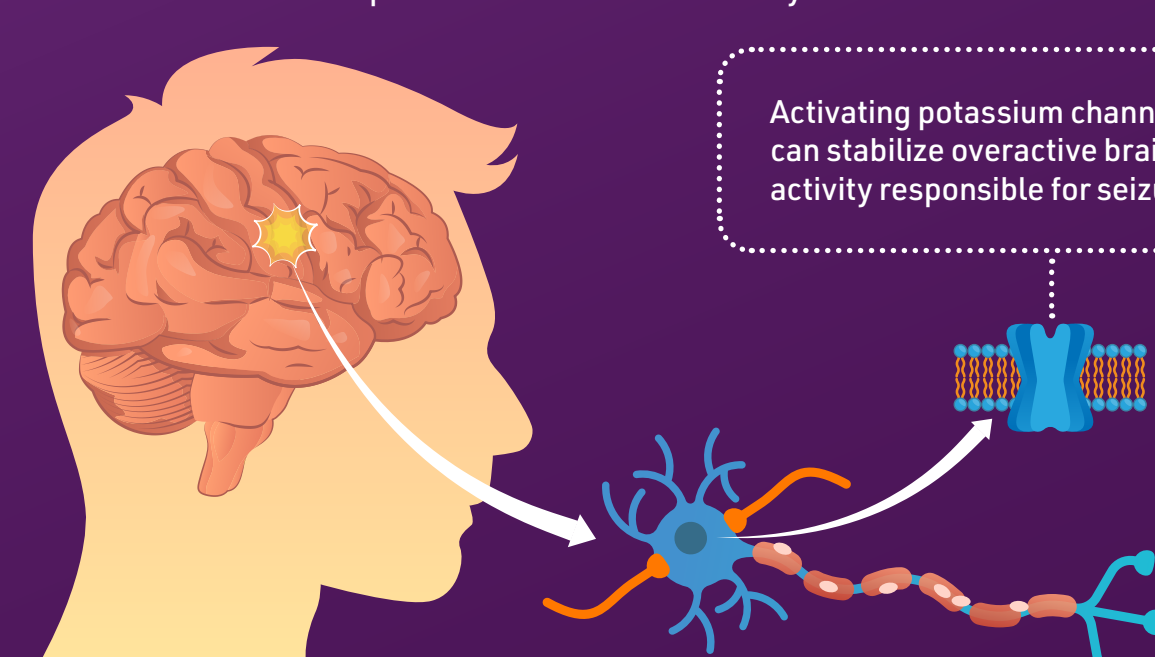
Have been diagnosed with idiopathic generalized epilepsy with GTC seizures for at least six months

Are receiving one to three anti-seizure medications (ASMs)

Have had at least three days with a GTC seizure evenly spread over the 16 weeks immediately prior to the screening visit

BHV-7000

BHV-7000 works on a part of the nerve cells in the brain called potassium channels, which help balance the electrical activity in the brain.



Activating potassium channels can stabilize overactive brain activity responsible for seizures.

FOR MORE INFORMATION ABOUT THE TRIAL AND TO FIND A SITE, VISIT EPILEPSYRESEARCHSTUDY.COM

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1. World Health Organization. Epilepsy. Available at <https://www.who.int/news-room/fact-sheets/detail/epilepsy>. Accessed June 6, 2024.
2. Kobau R, Luncheon C, Greenlund KJ. About 1.5 million community-dwelling US adults with active epilepsy reported uncontrolled seizures in the past 12 months, and seizure control varied by annual family income-National Health Interview Survey, United States 2021 and 2022. Epilepsy Behav. Published online May 30, 2024. doi:10.1016/j.yebeh.2024.109852.
3. Epilepsy Foundation. Understanding Seizures. Available at <https://www.epilepsy.com/what-is-epilepsy/understanding-seizures>. Accessed June 6, 2024.
4. US Centers for Disease Control and Prevention. Types of Seizures. Available at <https://www.cdc.gov/epilepsy/about/types-of-seizures.html>. Accessed June 6, 2024.
5. Ioannou P, Foster DL, Sander JW, et al. The burden of epilepsy and unmet need in people with focal seizures. Brain Behav. 2022;12(9):e2589. doi:10.1002/brb3.2589.