

About the Lighthouse Clinical Study

The purpose of the Lighthouse clinical study is to evaluate the safety and efficacy of the investigational medication, clemizole, as an additional therapy to potentially lower the number of seizures in children and adults living with Lennox-Gastaut syndrome (LGS). If someone you care about has frequent seizures from LGS, even when taking antiseizure medication(s), this clinical study may be an option.

About the Investigational Medication

The investigational medication, clemizole, is an oral solution that will be administered twice a day during the study.

Participants will have a 1 in 2 (50%) chance of receiving either the investigational medication, clemizole, or a placebo (a liquid that looks like the investigational medication but contains no active medication) for the first 4 months of study treatment. Neither you nor the study staff will know which one the participant is receiving.

Participants who complete the first 4 months of the study will have the ability to continue to receive clemizole in the optional extension period at no cost to them. Participants must remain on their antiseizure medications they are currently taking during the study.



Visit:

LighthouseLGSStudy.com



References:

1. Lennox-Gastaut Syndrome. National Institute of Neurological Disorders and Stroke. Accessed November 4, 2024. [https://www.ninds.nih.gov/health-information/disorders/lennox-gastaut-syndrome#:~:text=Children%2C%20adolescents%2C%20and%20adults%20with,Atypical%20absences%20\(staring%20spells\)](https://www.ninds.nih.gov/health-information/disorders/lennox-gastaut-syndrome#:~:text=Children%2C%20adolescents%2C%20and%20adults%20with,Atypical%20absences%20(staring%20spells))
2. Lennox-Gastaut Syndrome. LGS Foundation. Accessed November 4, 2024. [https://www.lgsfoundation.org/about-lgs-2/what-is-lennox-gastaut-syndrome/#:~:text=Many%20with%20LGS%20survive%20into,a%20seizure%20resulting%20in%20pneumonia\)](https://www.lgsfoundation.org/about-lgs-2/what-is-lennox-gastaut-syndrome/#:~:text=Many%20with%20LGS%20survive%20into,a%20seizure%20resulting%20in%20pneumonia))
3. Lennox-Gastaut Syndrome (LGS). Epilepsy Foundation. Accessed November 4, 2024. <https://www.epilepsy.com/what-is-epilepsy/syndromes/lennox-gastaut-syndrome#What-is-Lennox-Gastaut-syndrome?>

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You're focused on the moments that matter. So are we.

If you or someone you care about is living with Lennox-Gastaut syndrome (LGS), consider the Lighthouse clinical study.



How to Qualify

People living with LGS may be able to participate in this study if they*:

- Are at least 2 years old
- Were diagnosed with LGS
- Had onset of seizures before turning 11
- Have a lack of seizure control despite taking 1 to 4 antiseizure medications
- Have frequent seizures (an average of 4 seizures per month for the last 2 months)
- Are not enrolled in another clinical study

* This is not a complete list of study requirements. The study doctor will review all the requirements with you and/or the potential participant.

Why Participate

If the person living with LGS qualifies and decides to participate, they will receive:

- All study-related care and the investigational medication at no charge
- Assistance with study-related travel expenses (including food and lodging), as needed
- Close monitoring by a study doctor and study team who specialize in LGS
- The opportunity to help researchers learn more about LGS
- The opportunity to receive the investigational medication, clemizole, during a study extension at no cost

Safety while participating in the Lighthouse clinical study is our highest priority. If any questions or concerns arise, a study team member is available to help.



Participation in any clinical study is always voluntary. Participants are free to leave the study at any time and for any reason. Privacy will be maintained throughout the study.

What to Expect During the Lighthouse Clinical Study

The Lighthouse clinical study may last up to 3½ years, and includes 4 parts: Screening, Study Treatment, Long-term Extension, and Follow-up. Both clinic visits and phone calls will be required.

Seizure and Medication Diary

You will fill out a seizure and medication diary at home to keep track of the participant's seizures and when they take the investigational medication. The seizure diary is important to help researchers understand the effects of the investigational medication on the participant's seizures.

About Lennox-Gastaut Syndrome

LGS is a rare type of severe epilepsy that develops in young children.¹ People living with LGS have more than 1 type of seizure, and their seizures happen frequently.²

People living with LGS commonly have delays in their development and intellectual abilities that can get worse as they get older.³ They may also have behavior problems, including hyperactivity, aggression, and difficulty paying attention.²

Many medicines available today do not reduce seizures enough for people living with LGS, even when taking multiple medicines.³

About LGS Research

A clinical study, also called a clinical trial, is conducted to learn whether an investigational medication is safe and effective for use in people with a particular medical condition, such as LGS. Clinical studies must follow strict scientific standards to help ensure the safety of the participants while researchers learn more about the investigational medicine.

Clinical studies such as the Lighthouse clinical study depend on volunteers to participate and help researchers learn more about the effects of an investigational medicine.

Learn more at:
LighthouseLGSStudy.com