

# THE LGS DISCOVER STUDY

A Clinical Study For  
Children and Adults with  
Lennox-Gastaut Syndrome

## About this Study



SK Life Science, Inc., a subsidiary of SK Biopharmaceuticals Co., Ltd., an innovative global pharmaceutical company focused on developing treatments for central nervous system (CNS) disorders, is conducting a clinical study to evaluate the efficacy and safety of carisbamate for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS).

## What is the Purpose of this Study?

Currently approved antiseizure medications (ASMs) do not always successfully control LGS seizures. The LGS DISCOVER study (YKP509C003) is looking to see whether an investigational medicine called carisbamate, when given alongside other ASMs, can decrease the number of seizures in children and adults aged 4-55 years with LGS.

## What are the Goals of this Study?

The goals of the LGS DISCOVER study are to see if/how:

- Carisbamate reduces the number of seizures compared with placebo when given with ASMs in children and adults with LGS.
- The study drug affects the ability of participants to carry out daily activities.
- Participants with LGS can tolerate the study drug and how safe it is.

## Who Qualifies?\*

- Patients diagnosed with LGS
- Patients between the ages of 4 and 55
- Patients with eight (8) or more major motor drop (MMD) seizures each month
- Patients who are currently taking one (1) to four (4) ASMs at a stable dose

\* Patient eligibility will be assessed by study staff based on study criteria.

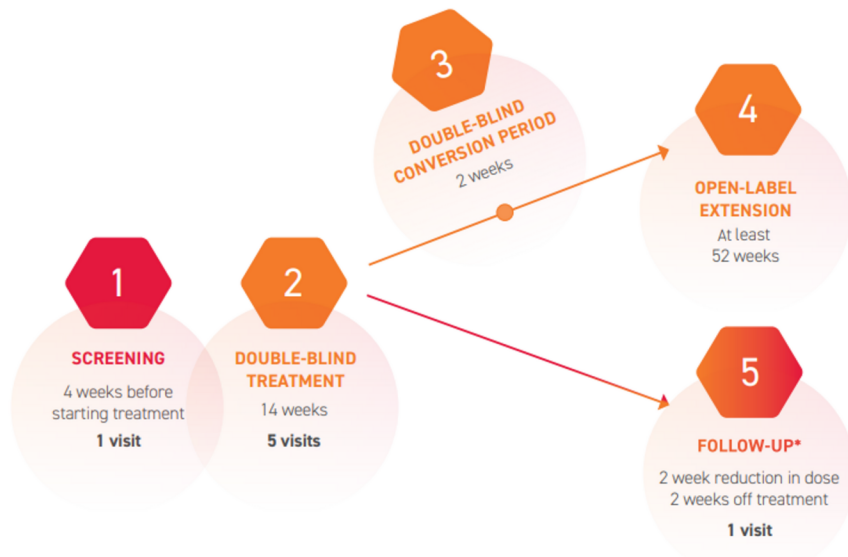


## What happens during the study?

The first portion of the study is double-blinded, meaning neither you/your child nor the study team will know which treatment you/your child is receiving. This part of the study will compare the study drug (carisbamate) to a placebo (no active ingredients) as an add on to patient's current ASM.

After completion of double-blind treatment, there is an optional extension study for eligible patients. Everyone in the extension study will receive the study drug. Before entering the open-label extension, participants will undergo a 2-week double-blind conversion period.

For participants who stop treatment early or do not wish to enter the open-label extension, there is a 4-week follow-up period.



\*Participants who do not join the extension study  
MED-US-CA-0001 - YKP509C003 Study Flyer (v1.0)

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### SCREENING (4 weeks):

The first step is to go through the Informed Consent process, during which you will learn about the study. The goal of this consent process is to make sure you understand the requirements of the study, the possible risks and benefits of participating in the study, and to give you a chance to ask questions. You will receive an Informed Consent Form to read that explains the study. Signing the form means you give permission for you or your child to be part of the study. Children joining this study may also sign an Informed Assent Form. After that, there will be health checks and tests. Participants will continue to take their ASMs during this period and will receive a paper seizure diary that needs to be completed every day.

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### DOUBLE-BLIND TREATMENT (14 weeks):

The seizure diary will be reviewed by the study team. Participants will then be assigned by chance (like flipping a coin) to 1 of the 3 treatment groups (two active groups and one dose-match placebo). Clinic visits (Visits 2 to 6) during this period will be on Days 1, 15, 43, 71, and 99. During these visits, the seizure diary will be collected, the study drug will be given to participants, and health checks and tests will be done.

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### DOUBLE-BLIND CONVERSION PERIOD (2 weeks)

Participants who complete the double-blind treatment period will have the chance to enter the open-label extension period. Participants will enter a 2-week double-blind conversion period. During this 2-week period, participants will be transitioned to the study drug. At the end of this 2-week period, all patients will enter the open-label extension and will be treated with carisbamate.

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### OPEN-LABEL EXTENSION (at least 52 weeks):

All participants will receive the study drug, carisbamate. Clinic visits will occur monthly for the first 3 months then every 3 months thereafter or as needed.

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### FOLLOW-UP (4 weeks):

Participants who decide not to enter the open-label extension study will need to attend an end of study visit (Visit 6). After this, the dose of the study drug will be reduced gradually over 2 weeks. There will be a further follow-up visit (Visit 7) 2 weeks after the final dose of study drug. During this follow-up visit, familiar health checks and tests will be done.

To learn more about this study, please see enrollment information at [www.LGSDISCOVERStudy.com](http://www.LGSDISCOVERStudy.com) or email [SKLSicarisbamate@sklsi.com](mailto:SKLSicarisbamate@sklsi.com).