

What risks are involved if I decide to participate?

There are possible risks involved with any clinical study. Your study doctor will review the risks with you, and you will be closely monitored throughout the study.

What is a clinical study?

In a clinical study, participants are assigned to one or more investigational drugs to answer questions about the treatment to see if it works, works better than other treatments, and has side effects.

What is an investigational drug?

An investigational drug is a substance that is being tested in clinical studies. It has been reviewed by an ethics committee for testing in people and may or may not be approved by the government health agency for treatment for this condition.

Why should I take part in this study?

Clinical studies (also called clinical trials) are important for medical advances. Current treatments for diseases are only available because of research study volunteers.



BHV3000-311

Thank you for your interest in this migraine study in children and teens.

For more information, please contact:

Reference: 1. Aydin M, Kabakus N, Bozdog S, Ertugrul S. Profile of children with migraine. *Indian J Pediatr.* 2010;77:1247-51.



BHV3000-311_patient_brochure_v1.0_02Mar2021_English



BHV3000-311

Now Enrolling: Migraine Study in Children and Teens

A study for children and teens
6 to 17 years of age with a history
of moderate or severe migraine

Ask your doctor if you are eligible for this study. For all study tests and assessments, “you” refers to the enrolled study participant.



Why is this study important?

Currently, more than half of pediatric patients with migraine have 1 to 4 attacks per month, causing interference with their daily activities of life.¹ Although many studies have been done in adults with migraine, doctors continue to research treatment options for migraine in children and teens through clinical studies.

In this study, doctors want to evaluate the safety and efficacy of a dissolving tablet called rimegepant in children and teens 6 to 17 years old. Rimegepant is approved by the US Food and Drug Administration (FDA) for the acute treatment of migraine in adults.

Pharmaceutical companies use clinical research studies like this one to learn more about investigational drugs before they are made available to the public. Study volunteers can help us in this important research. Thank you for considering participation in this study.



What is the purpose of this study?

This study is investigating the study drug (rimegepant) to find out how well it works compared to the placebo. Rimegepant is considered investigational in this study because it has not been approved for use in children and teens for migraine. Placebo is a substance that looks like the study drug but has no active drug in it.

Who can participate in this study?

To be eligible for this study, you must:

- Be 6 to 17 years old
- Have a history of migraine for 6 months or longer
- Have a history of 1 to 8 moderate or severe migraine attacks (lasting more than 3 hours without treatment) per month during the past 2 months
- Be able to understand the assent form and have parent(s)/caregiver(s) who can give informed consent

This is not a complete list of study requirements. The study doctor will review the full requirements for this study with you.

How long will this study last?

This study will last up to 19 weeks, and you will need to come to the study center up to 4 times over this period. Each office visit will generally last 1 to 2 hours.

What can I expect if I decide to participate?

Before any study-related tests and procedures can be done, you will be asked to read and sign some important forms. After you sign these forms, the study will begin with a screening visit to see if you meet the requirements to be in this study.

If the study doctor decides you are eligible to join the study, you will be randomly assigned (like the flip of a coin) to receive either rimegepant or the placebo treatment. You and your parent/caregiver will not be told which treatment you receive.

During the treatment period, you will treat up to 2 migraine attacks of moderate or severe pain with the study drug. Within 7 days of taking the study drug, you will be asked to return to the study center for a visit. If you do not experience a migraine during the study treatment period, you will be asked to attend just the end of treatment visit.

Lab tests, physical exams, and other assessments and questionnaires will be conducted as part of this study.

What are my costs to take part in this study?

You do not have to pay for the study drug, study supplies, or tests that are part of the research study.

