

If you are six to 17 years of age and experience migraine headaches, we invite you - along with a parent or caregiver - to talk to your doctor about a new clinical research study.

ABOUT CLINICAL RESEARCH STUDIES

What is a clinical research study?

A clinical research study looks at a study medicine to see if it is safe, how it works in the body, and if it works to treat a specific disease. The term "study medicine" means that the medicine has not been approved for this use by a regulatory health authority. Many treatments used today are the results of past clinical research studies. You should feel fully informed about what to expect from participation in a clinical research study.

Why are clinical research studies needed in children?

Some conditions affect only children. Also, adult treatments may not work the same in children, or there may be another form of medicine that is better suited for children. It is important for researchers to understand the safest and most effective treatments for children across all age ranges.

What can I expect from the PIONEER-PEDS1 Study?



Before participating, a detailed description of the study, as well as possible risks and benefits, will be discussed with you and your family.



Your parent will be asked to review and sign the informed



Study participation is voluntary. You have the right to withdraw from the study at any time.

Thank you for considering the PIONEER-PEDS1 Study.





PIONEER-PEDS1



A NEW OPTION TO THINK ABOUT

Your mind shouldn't be focused on migraines. Instead, your thoughts should be on school, activities, and friends. But migraine headaches can interfere with your everyday life. In addition to the unpredictability, you have to deal with the pain and other symptoms that are unique to you. Trying multiple treatments to find one that works can be frustrating. But what if you had another option to consider?

If you and your family are still trying to find a medicine that works for you, this clinical research study may be of interest. Research is currently underway on a potential new treatment option for children and teenagers with migraine headaches, and you may be able to take part. If this sounds like something you may be interested in, we encourage you to discuss the idea with your parent or caregiver. From there, your doctor will help you decide if this may be an option for you.



ABOUT THE PIONEER-PEDS1 STUDY

For this clinical research study, we are looking for children and teenagers ages six to less than 18 who have had a history of migraine headaches for more than six months. The goal of the PIONEER-PEDS1 Study is to investigate a new medicine, called lasmiditan, for migraine headaches. In this study, lasmiditan will be compared to placebo, which looks the same as lasmiditan but does not contain any active medicine. You will not know whether you are receiving lasmiditan or the placebo. This allows researchers to learn if the study medicine is working.

The PIONEER-PEDS1 Study consists of a screening visit, enrollment visit, treatment period, and end-of-study visit.

- The screening and enrollment visits are used to determine whether you qualify to participate in the study. If you do, you will be randomly placed in a treatment group during your second visit.
- During the treatment period, you will have up to 12 weeks to treat
 one migraine with the study medicine. You will use an e-Diary
 (an app on a device) not only to help you find the right migraine
 to treat, but also to guide you through taking study medicine and
 reporting how you feel.

ALONG WITH YOUR PARENT, CONTACT THE STUDY DOCTOR LISTED BELOW IF YOU ARE INTERESTED IN THIS STUDY

Study Doctor: Jessica Gautreaux, M.D.

Study Coordinator:

Address: 200 Henry Clay Ave

City, State Zip: New Orleans, LA 70118

Phone: 504-896-9319

