Migraine Clinical Trials: Exploring Clinical Trial Experiences of Patients with Migraine

An informed consent form for migraine patients in Power Clinical Trial's observational clinical trial.

Date: December 28, 2022

Migraine Observational Study Overview

Migraines are a common and debilitating type of headache that can significantly impact an individual's quality of life. Despite their prevalence, there is still much that is unknown about migraines, including their causes and potential triggers.

The purpose of this observational study is to gather more information about migraines and the enrolment experiences of individuals living with the condition. It will involve recruiting a diverse group of participants who have a diagnosis of migraines and following them over a period of time to gather data about their participation experiences and the progression of their condition. Participants in the study will be asked to complete periodic questionnaires and undergo physical examinations if needed.

The information gathered from this study will help to improve our understanding of the experience patterns of migraine patients. Being in this clinical trial is different from being a patient. This document can also serve as a summary of the discussion you have with the recruitment staff /researcher. It can also be reference material for you as you continue the trial process.

What are some things that I need to know about this study?

1. You can choose to participate in this study or not, and you can stop participating at any time. It is normal for people to withdraw from their studies.

2. This study is observational, which means that your participation will not change the medical care you receive. An observational clinical trial is a type of research study in which participants are observed and their outcomes are measured, but the investigator does not manipulate any variables or intervene in any way. Observational clinical trials are used to gather data and gather information about the natural history of a disease or condition, as well as to assess the effectiveness of interventions that are already in use.
3. The staff working on this study will not be able to diagnose conditions, prescribe medications, or manage your care.
4. If you do not understand anything that the staff says during this study, it is important that you tell them.

Why is this migraine clinical trial being done?

This study looks at the experiences of people who have participated in clinical trials for migraines. The goal is to identify what factors may make it difficult for people to participate in or complete a clinical trial that they are interested in. The study will collect data from participants about their clinical trial experiences and will look at this data through the lens of different demographic groups (such as age, gender, and race) to see if there are patterns that can be identified. The hope is that this information will help to improve the experience of future migraine patients participating in clinical trials.

Are there any risks if I decide to participate in this clinical trial?

This clinical trial involves online reporting and video conference calls with participants throughout the trial process. It is important to carefully consider the risks and benefits of participating in any clinical trial, including the potential for altering treatment regimens. However, this observational study will not directly impact your treatment regimen in any way.

One potential risk of participating in this trial is a breach of confidentiality, which could involve the disclosure of information about your participation in the study. However, the risk of such a breach is minimal and the risk of identity theft is limited by the measures we have in place to protect your data, such as encryption, password protection, and secure storage in a locked office. It is necessary to use and analyze the data collected in this investigation.

Is there any benefit if I decide to participate in this clinical trial?

The findings from this medical research may help increase the participation and diversity of enrolled patients in future clinical trials focused on recruiting people with migraines.

How does this trial compare to other studies for migraine?

While there are other clinical trials available for patients with migraine, many of these are interventional clinical trials, which require patients to follow a specific course of treatment. In contrast, this clinical trial is an observational study, which means that it will not involve the provision of any treatment.

We do not have a comprehensive understanding of all the clinical trials that are currently available for lung cancer. However, if you are interested in learning more, you can find information about migraine trials on clinicaltrials.gov or search for other migraine clinical trials on Power's participant reference site.

What is required of me as a patient with a migraine?

As part of this trial, you will be asked to complete bi-weekly surveys that will take approximately 30 minutes each. You will also have quarterly check-in calls with our team throughout the duration of your participation in this trial.

It is a requirement that you are enrolled in a separate interventional clinical trial in order to participate in this observational study. However, the details of that interventional clinical trial, including your treatment and the methodology used, will not be affected by this study. If you have any questions about the interventional clinical trial you are enrolled in, please reach out to your care team for more information.

Where can I learn more about representation in clinical trials?

There have been a number of studies conducted on clinical trial participation rates. Some examples of these studies are listed below:

Clark, Luther T., Laurence Watkins, Ileana L. Piña, Mary Elmer, Ola Akinboboye, Millicent Gorham, Brenda Jamerson et al. "Increasing diversity in clinical trials: overcoming critical barriers." *Current problems in cardiology* 44, no. 5 (2019): 148-172.

Knepper, Todd C., and Howard L. McLeod. "When will clinical trials finally reflect diversity?." (2018): 157-159.

Participant Statement

I confirm that I have read and understand the information provided above and that all of my questions have been answered to my satisfaction. I understand that my participation in this study is voluntary and that I am free to withdraw at any time. Signing this form does not affect my legal rights in any way. I will be provided with a copy of this consent form. By signing below, I indicate my agreement to participate in this research study.

_____

Printed Name of Participant

_____

Participant Signature

_____

Date

Statement of Person Conducting Informed Consent Discussion

I have explained the information in this document to the participant and, in my opinion, the patient understands the risks, benefits, alternatives, and procedures associated with this research study.

_____

Printed Name of Person Conducting Informed Consent Discussion

_____

Person Conducting Informed Consent Discussion Signature

_____

Date