An Observational Study Assessing the Experience of Patients Undergoing Active Cluster Headache Clinical Trials

This is an informed consent form for cluster headache patients participating in Power Clinical Trial's observational study.

Date: July 28, 2023

Introduction

We extend an invitation to you to take part in a non-interventional research study focusing on cluster headache. Your participation in this study is entirely voluntary, and you retain the freedom to withdraw your consent at any point during the research if you wish to do so. The reason for this invitation is that you are presently enrolled in an active clinical trial for cluster headache.

Should you decide to join this study, we kindly request you to sign the enclosed consent form. By doing so, you confirm that the study has been thoroughly explained to you, all your inquiries have been addressed, and you willingly grant permission to participate. It is vital to note that your involvement in this research will not in any way alter the regular medical care you receive from your doctor.

Purpose

The objective of this study is to gather information regarding the potential benefits of new investigational tests in predicting suitable medications for specific patients. It is important to note that these tests are solely intended for research purposes at this time.

Through this study, we seek to observe and comprehend various factors that influence your cluster headache clinical trial enrollment process and how they may impact your ability to participate and successfully complete the trial.

The collected results will be anonymized to ensure confidentiality and will be analyzed to identify trends related to the experiences of cluster headache patients, which often contribute to unsatisfactory enrollment rates or low completion rates.

As this clinical study is purely observational in nature, your treatment will remain unaffected should you choose to participate.

This document serves as written confirmation of all discussions you have had with our site staff or recruitment coordinators, and you may also utilize it as a point of reference throughout your participation in this clinical study.

Study Activities

Your involvement in this study will require your presence in bi-weekly surveys, with each survey estimated to last around 30 minutes. Additionally, there will be quarterly check-in calls scheduled throughout the clinical trial process.

To be eligible for participation in this observational study, it is a prerequisite that you are currently enrolled in an interventional clinical trial. It is important to emphasize that your ongoing treatment and the methodology prescribed by your primary care doctor will remain unaffected should you choose to join this study.

Throughout the trial, we encourage you to reach out to our staff if you have any concerns or questions that require clarification or assistance.

Before enrolling in this clinical study, we kindly request that you seek approval from your care team and discuss your intention to participate with them.

Participant Responsibilities

This study does not impose any mandatory visits or treatments. Instead, relevant health and medical information will be entered into the study database by the study doctor or staff during your regularly scheduled appointments.

Throughout your participation in the study, it is of utmost importance to promptly notify the study doctor or staff about any changes in your health or well-being.

Should you wish to withdraw from the study at any point, kindly inform the study doctor or staff. In the event that they are unable to contact you despite repeated attempts during the study, they may reach out to a person listed on the disclosure form on file at the study center to obtain updated contact information or to be informed about any changes in your health.

Potential Benefits

It is important to note that participating in this study will not result in any direct benefits for you. Nevertheless, the information derived from this study could be of immense value to researchers, aiding them in comparing outcomes with other observational studies that explore patients' experiences in similar clinical trials.

Potential Risks

It is essential to acknowledge the possibility of a risk that your protected health information could be exposed, leading to your identification. However, we have taken measures to protect your identity and the associated data and samples collected by utilizing a coding system consisting of letters and numbers. The coded data may be retained for an extended duration. To learn more about the duration for which your coded samples might be stored for research purposes, kindly consult the study doctor or study staff.

Furthermore, it is crucial to understand that your genetic test results may be accessible to your insurance company, other medical practitioners, and various other entities. To safeguard individuals, the Genetic Information Nondiscrimination Act (GINA) has been enacted, making certain types of genetic discrimination illegal. Under this federal law, health insurance companies, group health plans, and most employers are prohibited from discriminating against you based on your genetic information. However, it is essential to be aware that GINA does not provide protection against discrimination from companies that offer life insurance, disability insurance, or long-term care insurance.

Comparing This Trial To Other Cluster Headache Clinical Trials

Diverging from conventional cluster headache trials, this study employs a distinctive observational approach. Unlike interventional clinical trials that focus on specific

treatments, this study centers around thorough observation and comprehensive data collection.

As a participant in this observational clinical trial, you can take comfort in knowing that your current treatment plan will remain unaltered, and no treatment recommendations will be made. The primary aim is to accumulate a wealth of data and insights about cluster headache and their profound impact on patients' lives. By choosing to be part of this study, you have the chance to make a substantial contribution to the existing pool of knowledge and potentially influence future advancements in cluster headache care.

For individuals seeking alternative research opportunities, clinicaltrials.gov serves as a valuable resource for exploring ongoing cluster headache studies. Additionally, Power's online page provides a dedicated section specifically focusing on cluster headache clinical trials, offering a plethora of information for those eager to delve deeper into available prospects.

Other Resources To Read On Diversity in Clinical Studies

For individuals seeking a deeper understanding of participation rates in clinical trials, a treasure trove of enriching experiences awaits through the following recommended sources. These references offer a wealth of information and comprehensive studies solely dedicated to exploring and unraveling the factors that significantly influence individuals' decisions to participate in clinical research:

Simon, Melissa A., Erika E. de la Riva, Raymond Bergan, Carrie Norbeck, June M. McKoy, Piotr Kulesza, XinQi Dong, Julian Schink, and Linda Fleisher. "Improving diversity in cancer research trials: the story of the Cancer Disparities Research Network." Journal of Cancer Education 29 (2014): 366-374.

Hwang, Thomas J., and Otis W. Brawley. "New federal incentives for diversity in clinical trials." New England Journal of Medicine 387, no. 15 (2022): 1347-1349.

Alternatives to This Study

Please be aware that this study does not offer treatment for your cluster headache condition. You have the option of choosing not to participate in this study as an alternative. Rest assured, your decision to be part of this study will have no impact on the care provided by your regular doctor. Similarly, should you decide to discontinue

your participation, it will not affect the treatment approach your regular doctor has for managing your cluster headache.

New Information

Throughout the study, your study doctor or study staff will keep you informed of any new information that may arise and could potentially influence your decision to continue your participation in the study.

Contacts

At any stage of the study, you are welcome to seek clarification by asking questions. Should you have any questions, concerns, or complaints about the study, do not hesitate to call the study doctor or study staff using the phone number provided on page 1 of this form. In the event of any injuries or illnesses during the study that you believe may be connected to your participation, please contact our study researcher without delay.

Consent to Participate

After carefully reading and discussing this form with my study doctor or the study staff, all my questions have been satisfactorily answered. I hereby give my voluntary agreement to participate in this study.

I also authorize the use and sharing of my records in connection with this study, as explained above. My signature on this form does not relinquish any of my legal rights as a research participant. I will be provided with a signed copy of this consent form for my own records.

_____

Printed Name of Participant

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Participant Signature

_____

Date

A comprehensive briefing on this study, encompassing its purpose, procedures (if applicable), potential risks, benefits, and the voluntary nature of participation, has been given to the participant. The opportunity to seek clarifications through questions was extended, and I have diligently responded to all inquiries raised by the individual. Furthermore, to ensure transparency, a signed copy of this form has been furnished to the participant.

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Printed Name of Person Taking Consent

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Signature of Person Taking Consent

_____

Date