The Patient Voice in Narcolepsy Clinical Trials: Reflections on Experiences and Outcomes

This is an informed consent form for narcolepsy patients joining Power Clinical Trial's observational clinical study.

Date: May 12, 2023

Narcolepsy Clinical Study Overview

Narcolepsy is a neurological disorder that affects a person's ability to regulate sleep-wake cycles. People with this illness may experience excessive daytime sleepiness, sudden and uncontrollable episodes of falling asleep during the day, sleep paralysis, and hallucinations. These symptoms can significantly impact daily life and can potentially lead to accidents or injuries. While the exact cause of narcolepsy is not fully understood, it is believed to be related to a deficiency in a neurotransmitter called hypocretin, which helps regulate wakefulness. There is currently no cure for it.

An observational trial can provide a platform for patients to share their experiences and perspectives on living with narcolepsy, which can inform the development of new treatments and support programs. Overall, an observational clinical trial is an important tool for advancing our understanding of narcolepsy and improving outcomes for patients.

The objective of this study is to gain insight into the reasons why participation or completion rates among narcolepsy patients may be lower during clinical trials. To achieve this, we are inviting you to take part in an observational clinical trial. The study will aim to identify any patterns in the patient experience that may be contributing to these rates. Please note that the information you provide during the trial will be kept anonymous and carefully analyzed.

It is important to understand that this trial is strictly observational, and no changes will be made to your treatment plan. Participating in this trial does not involve receiving any form of treatment. This document includes information about the recruitment process

and the staff involved in the trial, which you can refer to as needed throughout the trial process.

Introductory Notes

Taking part in this study is voluntary, so you can choose to stop participating at any time if you wish. It's typical in medical research studies. It's important to remember that your treatment will not be impacted if you choose to participate in this study. This is an observational study, which implies that if you are currently receiving treatment, your diagnosis, medications, and care will remain the same. The study team will not be allowed to interfere with your treatment or monitor your care status.

Furthermore, it's essential to ask for clarification if you don't understand something at any point during the study. If you have any questions or are unclear about instructions or explanations, please do not hesitate to inform the team.

The Importance of Conducting Narcolepsy Research

Clinical trials in the past have been limited to specific demographic groups. However, there is a scarcity of research on the factors that may hinder the participation of narcolepsy patients in these trials.

This research study seeks to gather comprehensive information from participants to identify consistent factors that may prevent individuals from enrolling or completing the study. The collected data will be thoroughly examined from various demographic perspectives to identify patterns that may affect the experiences of future narcolepsy patients. By participating in this study, you can provide valuable insights that may enhance the participation and completion rates of narcolepsy patients in clinical trials.

Clinical Trial Process

Enrollment in an interventional clinical trial is required to participate in this study. It's important to note that participation in this observational clinical study will not impact your existing narcolepsy care regimen if you are part of a different clinical trial. If you have any concerns or questions regarding your interventional clinical trial, please reach out to your care team for additional information.

As a participant in this observational clinical study, you will be asked to complete bi-weekly surveys that will take approximately 30 minutes to complete. Additionally, there will be quarterly check-up calls scheduled throughout your interventional clinical trial, which are separate from this observational research. Please ensure that you schedule these calls as required.

Potential Risks and Benefits of Participating in an Observational Clinical Trial

Participating in a medical study comes with potential risks. In this observational clinical trial, the risks include the possibility of changing care regimens, which could have negative consequences for the participant. However, this is not a concern in this particular study as it is purely observational. Your treatment will not be changed in any way. Another potential risk is the breach of confidentiality due to regular communication through video conferences and online reporting. We take steps to minimize this risk by using encryption and password protection to secure all electronic data.

On the other hand, participating in this study also has potential benefits. The results of this trial will provide valuable insights into the factors that may impact the participation and completion rates of diverse narcolepsy patients in clinical studies. This information will be useful for future clinical trials that aim to enroll people with narcolepsy. By participating in this study, you can contribute to a better understanding of the factors that may affect the participation of diverse patient populations in these trials.

This Observational Study to Other Narcolepsy Clinical Trials

Unlike many other clinical trials for narcolepsy patients, this study is purely observational, meaning that it does not require patients to receive any specific treatment regimen. The staff involved in this study may not have detailed knowledge about other narcolepsy studies. However, there are resources available. If you are looking for a comprehensive list of narcolepsy studies, head to ClinicalTrials.gov. Meanwhile, if you are looking for a list of narcolepsy clinical trials looking for participants, you can check Power's reference website.

Exploring Diversity in Clinical Trials: Recommended Reading

Although there is a scarcity of research on the representation of diverse populations in clinical trials, there are several studies that offer valuable insights. Here are some recommended readings that you may find interesting:

Kailas, Ajay, Morgan Dawkins, and Susan C. Taylor. "Suggestions for increasing diversity in clinical trials." *JAMA dermatology* 153, no. 7 (2017): 727-727.

Charrow, Alexandra, Fan Di Xia, Cara Joyce, and Arash Mostaghimi. "Diversity in dermatology clinical trials: a systematic review." *JAMA dermatology* 153, no. 2 (2017): 193-198.

Securing Your Privacy and Confidentiality in the Study

The protection of your personal information is a top priority in this clinical study. In order to keep your data confidential, we will assign a unique code or number to your records and any identifying materials will be kept in a locked file cabinet that is supervised by the researcher. We value your privacy and will not disclose any of your personal information without your explicit consent, except in cases where disclosure is required by law, such as in cases of abuse or suicide risk.

Consent

By signing this form, I acknowledge that I have been fully informed about the nature and purpose of this study. I understand that my participation is completely voluntary and that I may withdraw from the study at any time without any negative consequences. I also understand that I will be given a copy of this consent form.

_____
Printed Name of Participant

_____
Signature

_____
Date

Confirmation of Participant Understanding

As the clinical trial personnel responsible for discussing the consent form with the participant, I can confirm that they have fully comprehended the information provided. I am confident that the participant has a clear understanding of the risks, benefits, and procedures involved in this clinical research based on our discussions.

_____
Printed Name of Person Getting Consent

_____
Signature of Person Getting Consent

_____
Date