A Detailed Look At What Patients Experience When They Take Part In Hypertension Clinical Trials

This is an informed consent form for hypertension patients joining Power Clinical Trial's observational medical trial.

Date: June 9, 2023

Initial Overview

Hypertension, also known as high blood pressure, is a condition in which the force of blood pushing against the walls of your arteries is too high. High blood pressure often has no symptoms, so it's called a "silent killer." If left untreated, high blood pressure can damage your heart, brain, kidneys, and other organs.

An observational clinical trial to study hypertension can help researchers collect information about how hypertension affects people over time. Scientists can watch many people and see what they do every day. It helps doctors develop better strategies for preventing and managing hypertension. They can also see what works better for different people. These things help scientists learn more about how to help people and make them healthier.

For this observational clinical trial, we aim to gather data without introducing new treatments or altering your hypertension management plan. Our primary objective is to ensure that you clearly understand the study and feel at ease throughout the research process. If you have any uncertainties or require further information, we strongly encourage you to seek clarification without any hesitation. Our study team is readily available to address any questions or concerns you may have regarding instructions, explanations, or any aspect of the study.

This study is not intended to test any new treatments. Its purpose is to learn from you. You will receive the same treatment from your doctor as always. This paper will provide you with all the information you need about the study, including how to join it and who will work with you.

Study Purpose

This research study aims to identify the obstacles faced by specific demographic groups of hypertension patients during their engagement in clinical trials. The study will collect in-depth information from participants and identify common factors that impede their enrollment or successful completion of these trials.

By examining data from various demographic perspectives, the study aims to identify patterns impacting future hypertension patients' experiences. Your participation in this research is vital as it can offer insights to enhance hypertension patients' participation and completion rates in clinical trials.

What You Must Recognize and Agree To

You can start participating in the study at any time and stop participating at any time. No justification must furnish for starting or stopping; you will not be penalized for either decision.

This medical research study is voluntary and observational, so it will not affect your treatment plan. The study team will not interfere with your medical care or monitor how you are being treated.

Cost/Reimbursements

No charges or fees shall be imposed upon individuals in this study. The investigators will not compensate for any medical expenses arising from participation in the study.

Examining Interventional and Observational Studies to Facilitate Informed Decision-Making

To participate in a research study on hypertension clinical trials, you must enroll in an interventional clinical trial. If you already participate in another clinical practice focusing on pulmonary fibrosis, you can still join this observational clinical study without affecting your ongoing treatment regimen.

If you have any queries or issues, don't hesitate to contact us about participation in the interventional clinical trial. It would be best to run after for guidance and more information from your healthcare team. It is crucial to entirely understand the differences between interventional trials and how they may affect your health.

Participating Actively

To fully engage in this observational clinical study, completing surveys every two weeks is mandatory, which should not take more than 30 minutes. Moreover, specific quarterly follow-up discussions are planned for your participation in the interventional clinical trial. To participate actively in both research components, scheduling and attending these calls quickly according to the study's guidelines is essential.

Analyzing Potential Dangers and Precautions in the Study

Within this observational clinical trial context, it is crucial to emphasize the potential risks involved. As the study strictly follows an observational approach, there will be no modifications to the existing care protocols, ensuring the absolute avoidance of any adverse effects on the individuals taking part.

Additionally, to provide the highest level of confidentiality, we have implemented robust encryption mechanisms and rigorous password protection measures to enhance the security of all electronic data. These stringent safeguards effectively reduce the risk of unauthorized access or breaches during regular video conferences and online reporting, reinforcing the comprehensive data protection framework.

Probable Benefits

This hypertension clinical trial holds significant promise and should be thoroughly evaluated. The trial results will yield invaluable insights into the factors influencing the enrollment and retention rates of a diverse range of patients with hypertension in clinical studies.

This knowledge will be essential for enhancing future clinical trials involving individuals with hypertension, ultimately leading to improved understanding and management of this condition.

By actively participating in this study, you can make a meaningful contribution to advancing our understanding of the factors that impact the engagement of diverse patient populations in these trials. Your participation is voluntary, and you may back out anytime without losing the benefits to which you are otherwise entitled.

Differences Between This Study From Other Hypertension Clinical Trials

This hypertension clinical trial distinguishes itself from other investigations using an observational methodology. Participants in the test are not required to adhere to a specific treatment plan, allowing for a comprehensive examination of the natural course of hypertension and its associated factors. This approach provides valuable insights into the real-world management and outcomes of the condition.

While the study team does not know all research on hypertension, resources are available to provide assistance and guidance. Interested individuals can explore a wide range of hypertension studies listed on ClinicalTrials.gov, offering additional opportunities for future participation. Power's reference page is an excellent resource that provides an up-to-date compilation of persistent hypertension clinical trials actively seeking participants.

Investigating Inclusivity in Clinical Trials

We have compiled suggested readings that offer valuable perspectives on the limited research on the representation of diverse populations in clinical trials. These resources cover various topics and are both captivating and informative:

Nicholas, Susanne B., and Lilia Cervantes. "Health care equity and justice scorecard to increase diversity in clinical trial recruitment and retention." *Journal of the American Society of Nephrology* 33, no. 9 (2022): 1652-1655.

FOX-RAWLINGS, STEPHANIE R., Laura B. Gottschalk, Lauren A. Doamekpor, and Diana M. Zuckerman. "Diversity in medical device clinical trials: do we know what works for which patients?." *The Milbank Quarterly* 96, no. 3 (2018): 499-529.

These recommended readings serve as valuable resources, shedding light on the importance of inclusivity in clinical trials and providing deeper insights into the representation of diverse populations.

Effective Privacy Protection Measures

Preserving your personal information's privacy and confidentiality is a paramount concern within this clinical study. To ensure the utmost protection, we have implemented robust measures. Your records will be assigned a specific code or number, ensuring anonymity throughout the study.

All identifiable materials will be securely stored in a locked file cabinet, closely supervised by the researcher. We hold your privacy in high regard and are dedicated to refraining from disclosing any personal information without your explicit consent, except in situations mandated by law, such as cases involving abuse or suicide risk.

Confirmation of Voluntary Participation and Consent

I, as a result of this, confirm, by signing below, that I have been provided with detailed information concerning the nature and objectives of this study. I comprehend that my participation in this study is entirely voluntary, and I can withdraw from it anytime without facing any negative consequences.

I sincerely appreciate the assurance that my decision to withdraw will not impact my current or future medical care. Additionally, I request a copy of this consent form for my records.

_____

Printed Name of Participant

_____

Signature

_____

Date

Ensuring the Participant's Awareness

As the person in charge of explaining the consent form to the participant, I am happy to verify that the participant has understood the risks, benefits, and procedures of this clinical research. By having clear and informative conversations, all doubts and questions are fully resolved, making sure that the participant has a good understanding of the outcomes and methods of the study.

_____

Printed Name of Person Getting Consent

_____

Signature of Person Getting Consent

_____

Date