

Parkinson's Disease Understanding Clinical Trials

What You Need to Know

Progress in treating Parkinson's disease (PD) depends on clinical trials, and the success of clinical trials depends on people like you who volunteer to enroll in a trial. In this fact sheet, you will learn about clinical trials, what they can offer you, and how you can learn more.

By participating in a clinical trial, you are helping to improve the understanding of the disease and the best way to treat it. All of the advances in treating people with PD have come about through clinical trials. Participation in any trial is voluntary, and should only be undertaken with a full understanding of risks and potential benefits.

Clinical Trials Overview

A clinical trial helps improve the understanding of treatment of a disease like PD. There are two types of clinical trials. An **interventional** clinical trial tests whether a treatment, such as a new drug or type of surgery, can offer more benefit to patients than current treatments. An **observational** clinical trial does not test a new treatment. Instead, it carefully observes some aspect of the patient's disease, such as tremor or speech, to better understand it, which may lead to better treatments in the future. A genetic study is a type of observational trial. Understanding the genes that increase the risk of PD, or what make symptoms worse, can help in the development of new therapies.

Both types of clinical trials are crucial for advancing the treatment and ultimately finding a cure for PD. When a new treatment for PD is developed, it must go through several stages of testing before the United States Food and Drug Administration (FDA) considers it for approval.

- A **Phase I trial** is performed in a small number of healthy individuals to determine if the treatment is safe enough to give to patients.
- A **Phase II trial** tests the treatment in a small number of people with PD. The major goals of a Phase II trial are to make sure the treatment is safe in patients, to determine the best dose, and to look for initial hints that the drug offers some benefit.
- A **Phase III trial** is performed in hundreds of PD patients at multiple centers, and tests whether the drug conclusively provides a benefit. The FDA considers both safety and benefit in determining whether to approve a drug for marketing.

For many people, receiving a new treatment, whether it's

helping or not, can temporarily improve how they feel, even in a disease such as PD. This short-term, psychologically driven improvement, called the **placebo effect**, makes it difficult to know whether a new treatment is truly providing benefit. Therefore, in a Phase III trial, the new treatment is often compared to a placebo. A placebo is a harmless substance (such as a sugar pill) that is made to resemble the new treatment. In a **double-blind** trial, neither the patient nor the physician knows whether the patient is receiving the new treatment or the placebo. In some cases, a new treatment is compared to an appropriate currently available treatment instead, to determine if the new treatment offers a significant improvement over one that is already available.

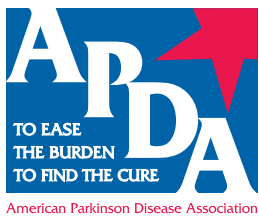
Meeting Current Challenges in PD Treatment Through Clinical Trials

While there are multiple types of drugs that reduce the symptoms of PD, there are none that address all of the symptoms. Researchers are currently developing promising new therapies that aim to better control PD symptoms with fewer side effects, and to lengthen the time that the medication works before wearing off. New treatments are also being developed to address PD's effects on thinking, emotions, behavior, and other "non-motor" symptoms. Research continues to try to develop drugs that can slow or halt the progression of the disease. Every one of these promising new ideas in PD treatment will need to be studied in clinical trials with PD patients who recognize the importance of joining the effort to find a cure for PD.

Participating in a Clinical Trial

Participation in a clinical trial is voluntary, and you have the right to withdraw from the trial at any time. Participating in an **interventional** clinical trial may offer you the chance to try a new treatment that may benefit you more than currently available treatments. Depending on the details of the trial, you may also have the opportunity to receive types of interventions you would not otherwise receive, such as physical therapy or dietary advice. However, participation may also expose you to some risks you would not otherwise be exposed to if you were not in the trial.

Most often, you will continue to see your regular doctor while you are involved in the trial. Your clinic visits may include some extra measurements that provide important data for determining the effectiveness and safety of the treatment.



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Supported through grants from:

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February 2016

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Informed Consent

Informed Consent is the process of learning about all of the possible risks and benefits of a clinical trial. You have a right to know these in detail prior to participating in a trial. The clinical team will discuss these with you, and you will be asked to acknowledge that you understand the information and to sign forms that indicate this. Be sure to ask as many questions as you need in order to fully understand what it will mean to you to participate in the trial. Your Care Partner should also be made aware of the risks and have an opportunity to ask questions.

Questions to Ask About Clinical Trials

- What have previous studies shown about the safety and effectiveness of the new treatment?
- What are the most common adverse effects seen with use of this treatment?
- How will the treatment team monitor me for adverse effects?
- Is there anything in my medical history that puts me at higher-than-average risk in this trial?
- What will I need to do during the trial, and how long will it last?
- Will I have to travel to a different medical center for any of my visits?
- What are the chances I will receive a placebo in this trial?
- Who should I contact if my condition worsens during the trial?
- Will I be able to continue on the new medication (or begin it, if I received a placebo) after the trial is over?
- What will it cost me to participate in the trial?

Costs Associated With Participating in a Clinical Trial

In general patients enrolled in a clinical trial are still responsible for their routine medical costs, such as regular office visits or non-trial medications. Insurance coverage for these routine costs is unlikely to change as a result of being in a trial, but it is important to confirm that with your insurance provider. Usually, there is no charge for receiving the study medication (or placebo) during the trial, or for other research-related activities, such as a test done specifically for the trial. Be sure to ask your physician or the trial coordinator (the person in charge of administrative aspects of the trial) about your specific situation.

Finding Out About Clinical Trials in Parkinson's Disease

You can search for clinical trials in PD at www.clinicaltrials.gov by entering "Parkinson's disease" into the search box. On the results page, you can refine your search to only show ones that are "open," or still enrolling patients. You can also restrict the results by topic or location.

Clinical trials represent the best hope for finding new treatments to improve the lives of all people with Parkinson's disease. APDA encourages you to consider participating in a trial that is right for you.

Resources

APDA provides information, education, and support to those impacted by Parkinson's disease and funds scientific research into the causes, prevention, treatments and ultimately the cure. We provide a nationwide network of programs, activities, and events to facilitate a better quality of life for the Parkinson's community. Through our website, www.apdaparkinson.org, you can find the full range of resources we offer, as well as links to other important sources of information and support.