CCF IRB #: 20-289
Approval Date: 5/5/2020
Expiration Date: 3/26/2021

ABOUT RESEARCH STUDIES

PARKINSON'S DISEASE

patients have more options to consider.

Research studies are different than regular medical care because the purpose of a research study is to gather information about an investigational drug. Pharmaceutical companies use studies like BouNDless to learn more about an investigational drug's safety and effectiveness.

Using what they learn from research studies, doctors and regulatory agencies can determine if an investigational drug could one day become available to the public. In order to conduct research studies, doctors need volunteers to participate in these studies. By participating in the BouNDless study, you could help make a difference in research for Parkinson's disease.

For more information, please contact:

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Learn more about the **BouNDless research study** of an investigational infusion for patients who have been diagnosed with Parkinson's disease and experience motor fluctuations.

BouNDless

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For many **PARKINSON'S DISEASE** patients, short-acting medications, like levodopa, help control their motor fluctuations.

However, as time passes and Parkinson's disease progresses, these patients face greater motor complications and unpredictable swings from mobility to immobility.

Different long-acting levodopa therapies have been approved, but some patients may find these therapies to be ineffective or inconvenient to receive. As a result, there is still a need for Parkinson's medications that give patients more control over their motor fluctuations, reduce time spent in "OFF" states, and are easily administered.

In the BouNDless study, doctors are evaluating an investigational drug solution of levodopa and carbidopa that is given subcutaneously over 24 hours via an infusion pump system.

Doctors want to learn whether the investigational drug and pump system can increase the time patients spend with their Parkinson's symptoms under control and do not experience motor fluctuations. The investigational drug and pump system have not been approved for treating Parkinson's disease and are only available in clinical studies like this one.

The results of this study will provide more information about the investigational drug and whether it could one day be used to better manage motor fluctuations in people with Parkinson's disease.

Who is eligible to participate in the BouNDless study?

To pre-qualify for this study, you must:

- Be at least 30 years of age
- Have been diagnosed with Parkinson's disease
- Experience motor fluctuations for at least 2 hours every day in the "OFF" state during your time awake
- Take at least 4 doses per day of levodopa/dopa decarboxylase inhibitor (or at least 3 doses per day of Rytary)
- Have a study partner to assist you throughout the study

All study-related visits, tests, and drugs will be provided to you at no cost. In addition, reimbursement for study-related expenses may be provided.

What will happen during the BouNDless study?

After a screening period of up to 28 days, in which the study doctor will determine if you meet the criteria to join the study, you will have your oral levodopa containing medications converted to immediate release levodopa/carbidopa. For 6 weeks, your doctor will adjust your medications to make sure your symptoms are managed as best as possible.

After those 6 weeks, you will be switched to receive an infusion of the investigational drug and additional oral levodopa/carbidopa as needed. For another 6 weeks, your doctor will adjust the infusion and your oral medications to make sure your symptoms are managed as best as possible.

Following these two periods in which your regimens were optimized, you will be randomly assigned (like the flip of a coin) to receive infusions of either the investigational drug or placebo for 12 weeks. Which mean that during this period you will receive both your oral levodopa/carbidopa regimen and your infusion regimen (which includes the extra levodopa pills if needed).

If you are randomized to receive placebo infusion, you will receive active oral levodopa pills. If you are randomized to the investigational infusion, you will receive placebo levodopa pills. You have an equal chance of receiving either study drug (investigational or placebo). Placebo looks exactly like the active drugs but contains no active medication.

You, the study doctor, and the study staff will not know which treatment you are receiving. However, in the event of an emergency, this information can be provided.

Your total study participation will last up to 28 weeks, which includes 19 visits to the study site for tests and assessments. At the end of the study, you may be given the opportunity to participate in an extension study in which all patients will receive the investigational drug for 12 months. During this period, your doctor can make adjustments to any of your PD medications, just like if it were an approved medication.

What are the benefits and risks related to the BouNDless study?

There is no guarantee you will benefit from participation in this study. However, your participation may help Parkinson's disease patients in the future.

It is possible you could experience a side effect while in this study. Before you join the study, the study staff will review the study-related risks and potential side effects with you.

Because research studies can affect the health of participants, you will be closely monitored throughout this study. The study sponsor was required to design a protocol, which explains the study in detail. An independent review board responsible for participant safety reviewed this protocol and requires that it be followed exactly.