Why is this study important?

For some people with Parkinson's disease, oral medications often "wear off" over time, which can lead to OFF episodes. As a result, additional doses of medication between regular doses may be required.

These doses can often be ineffective or slow to treat the OFF episode. Therefore, it's important to evaluate additional treatment options that can offer quicker relief from OFF episodes.

The results of this study will provide more information about the safety and effectiveness of the investigational medication. By taking part in this study, you will be making an important contribution to the treatment of OFF episodes in Parkinson's disease patients.

To learn more about this study, please contact:

<<Contact Name>>
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You have better things to do than worry about an **OFF** state.

Sometimes, Parkinson's patients need a way to bridge between doses. If you are having trouble controlling your Parkinson's symptoms throughout the day, please take a moment to learn more about this clinical trial.

When an OFF episode interrupts your day, all you want is for your medication to get you back to feeling like yourself as fast as possible. Unfortunately, oral medications for OFF episodes require time to take effect and can sometimes be unreliable. As a result, medications that help treat OFF episodes more quickly and effectively are still needed.

Local doctors are currently conducting a medical research study of an investigational medication that is inhaled through a special inhaler device. The investigational medication is a dry powder form of levodopa, which is commonly used for Parkinson's disease symptom management.

If you experience OFF episodes between doses of your Parkinson's disease medication, please read further for more details of this study.

What is the purpose of this study?

For most patients with Parkinson's disease, doctors use levodopa as a treatment to manage their symptoms. Levodopa pills have been used for many years to treat the symptoms of Parkinson's disease patients. However, long-term treatment with levodopa pills often lessens the effectiveness of the medication and can lead to OFF episodes, which includes slowness, stiffness, and tremors (shaking).

To help combat these OFF episodes, doctors will often allow levodopa to be taken between regular doses. These "between" doses of levodopa need time to take effect and can leave a patient in an OFF episode for an extended period of time. For many Parkinson's patients, this creates a need for treatment options that can rapidly be absorbed by the body and quickly treat the current OFF episode.

CVT-301, the investigational medication under evaluation in this study, is a dry powder form of levodopa. It is inhaled through an inhaler, which allows the body to absorb the medication faster than levodopa pills, which are taken orally.

Doctors believe that patients may be able to quickly find relief from an OFF episode by inhaling the dry powder form of levodopa when OFF symptoms start to return. The results of this study will provide more information about whether dry powder levodopa could one day be used to treat OFF episodes in Parkinson's disease patients.

Who is eligible to participate in this study?

To pre-qualify for this study, you must:

- Be between 30 and 80 years of age, inclusive
- Have a medical diagnosis of Parkinson's disease
- Experience a minimum of 2 hours of OFF episodes per day (excluding early morning OFF time)
- Be taking oral levodopa at least 4 times during the waking day, and on a stable levodopa regimen for at least 2 weeks prior to the study

All study-related visits, tests, and investigational medication will be provided to participants at no cost. The study will not provide you with your current Parkinson's medication. In addition, reimbursement for study-related time and travel may be provided.

What will happen during this study?

Before you can begin the study, you will be examined to determine if you are eligible to participate. If trial doctors and staff members find you to be eligible, and you agree to participate, you will be assigned to one of two study treatment groups.

If you have previously participated in a study of CVT-301, you will be assigned to the group that will receive treatment with CVT-301. If you have not received treatment with CVT-301 before, you will be randomly assigned (like the flip of a coin) to either the CVT-301 treatment group or the observational treatment group.

If you are assigned to the observational group, you will be permitted to use standard medical care for your Parkinson's disease for the entire study. You, the study doctors, and the study staff will know your group assignment.

You will also be shown how to use the inhaler during the screening visits. For the rest of the study, you will take your study medication at home for up to five OFF episodes per day, while continuing to take regularly scheduled doses of your Parkinson's medication.

Treatment with your study medication will last approximately 12 months. Total study participation will last about 13 months and includes 8 visits to the study clinic.

During your study clinic visits, doctors and the study staff will conduct various tests and assessments to evaluate your health and progress. These include, but are not limited to:

- Review of your medical history
- Physical exams
- Vital signs measurements (blood pressure, pulse, and respiration rate)
- Blood samples
- Breathing assessments
- Parkinson's disease assessments
- Reviews of medications you are taking
- Reviews of any side effects you experience

You will also be asked to enter information about your ON and OFF episodes into a diary and your use of study medication into a daily dosing log. You will need to bring these and any unused medication supplies with you to each clinic visit. In order to remain in the study, it is important that you attend all scheduled clinic visits and follow your study doctor's instructions.

What are the risks and benefits related to this study?

As with any medical research study, the treatment of your OFF episode may not improve with your participation in this study. While the investigational medication has been studied in patients before and was generally effective and well-tolerated, it is still possible you could experience a side effect.

You will be closely monitored while you are in this study. Researchers for this study were required to design a protocol, which explains all study procedures in detail. An independent review board responsible for participant safety approved this protocol and requires that it be followed exactly.

What if I have questions?

The study staff is always available to answer any questions or concerns you may have about the study or the investigational medication.