this research. Study doctor(s) and nurse(s) need to have access to the participant's medical records, as will the study sponsor and companies working on behalf of the study sponsor, the Institutional Review Board (IRB) and the Food and Drug Administration (FDA).

Withdrawing from the study

Participants are free to leave this study at any time. It will not affect present or future medical treatment; however, it is strongly advised to complete an end of study visit for final health evaluation(s).

What will it cost?

There are no charges for any study-related treatments, evaluations, tests, or procedures. The study sponsor will pay for these costs. Participants may be reimbursed for transportation costs for each office visit during study participation.

Patient Protections

The government agency, Food and Drug Administration (FDA), oversees the conduct of clinical research in the United States. The following are some of the actions that have been taken to protect study participant safety:

Institutional Review Board (IRBs) must review each study and each study site. Their job is to protect the rights and safety of research participants. IRBs are made up of doctors, scientists, and non-medical members of the community. They have the authority to approve, modify or stop any study based on all available information about its safety.

Informed Consent Document is for the protection of the rights and welfare of each research participant. The informed consent document explains everything needed to know about the study. It should be read carefully and ask as many questions as needed to fully understand what is written. The informed consent will explain the study drug, describe the procedures that are part of the study and explain any risks involved. It is your right to be fully informed about the study before consent to participate is given.

1. Fénelon G, Mahieux F, Huon R, Ziégler M. Hallucinations in Parkinson's disease: prevalence, phenomenology and risk factors. Brain 2000; 123:733-45. Marsh, L. Psychosis in Parkinson's disease. Primary Psychiatry, 2005; 12(7).

Rights to Privacy and Data Protection under the Health Information Portability and Accountability Act (HIPAA); ensures that personal information and privacy are protected. The US government created HIPAA to help ensure that an individual's personal health information will not be used or shared without permission. Study participants will be asked to sign an authorization form before participating in this study. This form will explain what health information will be collected from and how that information will be used. The research team will need to use participant's health information to manage their participation in this study.

Helpful Websites

The following websites may provide you with helpful information about Parkinson's Disease and participating in a research study:

National Parkinson Foundation
www.parkinson.org

The Michael J. Fox Foundation for Parkinson's Research
www.michaeljfox.org

Center for Information & Study on Clinical Research Participation
www.ciscrp.org

A National Registry of Clinical Trials
www.clinicaltrials.gov

*Sources The National Parkinson Foundation

Contact:

Study Coordinator: _____

Phone: _____

Principal Investigator: _____

Phone: _____

Protocol-020

V1.4 15JUN2010 (IRB Approved 16JUN2010)

Parkinson's Disease Research Study

Subject Information and Study Guide

Protocol-020

What is the purpose of this study?

There is an unmet medical need to find an effective treatment for Parkinson's Disease-related Psychosis (PDP) that does not have side effects that are especially worrisome in some patients with Parkinson's Disease. The study will research the safety and effectiveness of an investigational medication compared to placebo (an inactive look alike substance) in individuals with Parkinson's who are experiencing hallucinations and/or delusions (PDP).

What are the symptoms of PDP?

The most common symptoms of PDP are **hallucinations** (*seeing, hearing and/or feeling something that is not actually present*) and **delusions** (*believing in something that is not true, often including paranoid thoughts*).

What is PDP?

Psychosis is a medical term used to describe a loss of contact with reality that can lead to changes in a person's behavior and emotions. It is a real and serious problem that affects up to 40%[1] of patients with Parkinson's Disease at some point in their illness. It is felt that PDP is caused by the changing chemical levels in the brain, but the relationship between Parkinson's Disease (PD) and psychosis is complex and not completely understood.

Who can participate in this study?

Approximately 200 Parkinson's patients will participate in this study, which is being conducted at 50 locations across the United States.

To take part in this study, the individuals must meet the following eligibility criteria, although other criteria apply:

- Have been experiencing PDP symptoms for at least the past month
- Be at least 40 years of age with a Parkinson's diagnosis of at least 1 year
- Be on a stable dose of anti-Parkinson's medication for at least 1 month prior to study participation

The PDP Study Design

2 Week Screening Period	6 Week Study Treatment Period				4 Week Follow Up Period
	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
	Week 1	Week 2	Week 4	Week 6	Week 10
One study visit and two phone calls	Study visit Study Treatment starts Day 1	Study visit	Study visit	Study visit Study Treatment ends Day 42	One study visit unless joining extension study

Caregivers are a very important part of this study. Their input will be needed in assessing the health and behavioral changes of the subject. Caregivers will also be asked to report on any changes they personally have experienced while caring for the subject. Therefore, it is important that caregivers are able to accompany the subject to all study visits.

What is involved in participating?

Participation will last approximately 12 weeks (2 weeks screening period, 6 weeks study treatment period, and up to 4 weeks follow up period). Before a decision is made to take part in this study, detailed information will be given and all questions will be answered by the study staff.

If the subject qualifies for participation, they will randomly be placed into one of two study groups. Neither the participant nor the study doctor will know who gets placed into which group.

- Group 1: Investigational study medication to be taken by mouth once daily
- Group 2: Placebo to be taken by mouth once daily

At the end of this study, participants who complete the 6 week study treatment period will have the option to join an extension study where all participants will receive active investigational medication and no placebo will be used. Participation in this extension study is not dependent on the improvement of the subject's PDP symptoms in the first study.

Are there any risks?

All medications and treatments have risks. The study staff will thoroughly review the Informed Consent document with each subject, which includes a complete description of the known risks associated with this study treatment and study participation.

What are the benefits of this study?

The study treatment may reduce the subject's PDP symptoms, however, this cannot be guaranteed. Study participants and caregivers will also receive training in Brief Psychosocial Therapy (BPST), a technique performed between the caregiver and subjects that may reduce PDP symptoms in some subjects.

Study participation provides study-related assessments and evaluations that may provide the study doctor and subject with additional health information and potentially help researchers develop better treatments for people in the future. Study participants are contributing to the advancement of medical science and the study of PDP.

Confidentiality

We make every effort to maintain confidentiality and are compliant with laws and regulations that protect the privacy of medical information. Participant's names will not be revealed in any publications that may result from