

## **Clinical Trial**

### **Investigating the D<sub>3</sub> Dopamine receptor and its relevance to treatment-induced complications in Parkinson's disease.**

#### **What is Parkinson's disease?**

Parkinson's is a disorder of the brain. Movement is controlled by dopamine, a chemical that carries signals between nerves in the brain. When cells that produce dopamine die or are damaged, Parkinson's symptoms appear. Parkinson's is a complex condition causing motor symptoms, such as shaking, muscle stiffness, slowness of movement and impaired balance. Non-motor symptoms such as constipation, sleep disturbance, fatigue, depression and cognitive changes also occur. Current treatment neither cures Parkinson's nor stops it from advancing. (See Parkinson Society Canada's Information Sheet on *Progression of Parkinson's Disease* at [www.parkinson.ca](http://www.parkinson.ca))

#### **How is Parkinson's disease treated?**

Since Parkinson's is a progressive condition, symptoms will worsen over time and new ones may appear. Medications will need to be adjusted; perhaps taking them more frequently or at higher doses or a combination of drugs may be required to control symptoms. Some medications may have side effects such as dyskinesias (involuntary movements), sleepiness or changes in a person's behaviour. Impulse control disorders can be a side effect of some medications and include a range of behaviours such as compulsive gambling or shopping, hypersexuality, binge eating or addiction to the Internet. (See Parkinson Society Canada's Information Sheet on *Parkinson's Medications: What you need to know!* at [www.parkinson.ca](http://www.parkinson.ca))

#### **What is the goal of this study?**

The goal of this study is to understand how long-term treatment with medication for Parkinson's may lead to adverse side-effects. The specific aim of this study is to investigate whether medication used to treat Parkinson's changes the number of dopamine receptors. We will focus on a receptor called the D<sub>3</sub> dopamine receptor because of the recent finding from animal studies that it might be involved in treatment complications.

#### **What is being investigated?**

In this study, brain imaging technology will be used to measure brain levels of dopamine receptors. New imaging tools allow researchers to "look" inside the brains of people living with Parkinson's. This study will use Positron Emission Tomography, also known as a PET scan; and Magnetic Resonance Imaging, or MRI.

### **What kind of study is this?**

The study is a brain imaging study which includes three research groups; participants will not be receiving any additional medication in the course of this study. Depending upon their responses to their medication for Parkinson's, participants will be assigned to one of these groups: (1) levodopa-treated and stable; (2) levodopa-treated with dyskinesias; (3) levodopa-treated who have or have had behaviours associated with impulse control disorders. Our study will compare PET measures between these three groups to assess differences in dopamine receptor levels.

### **Who can participate?**

The study is seeking men and women over the age of 40 years who have Parkinson's disease and are taking levodopa (Sinemet, or generic). Individuals in the Greater Toronto Area and surrounding communities may participate. Participants should be either stable on their medication or show (or have shown) side effects from their medication including dyskinesias or impulse control problems. Participants should be medically fit, be able to understand/follow instructions, not receive treatment for any psychiatric disorder, have no history of alcohol or drug abuse, have no significant head injury, and have no metal implants

### **What is required of the participants?**

This study involves three stages:

- 1. Clinical interview** to assess suitability for inclusion in the study. The interview can last up to 2 hours. The person will be contacted if suitable for the study.
- 2. Brain imaging.** Two PET scans will be taken: one lasting 90 min, one lasting 60 min. The scans will be taken on the same day with a break in between (the break will be a minimum of 30 min, but will be determined in each case by scanner availability). If preferred, scans can also be taken on separate days. The total amount of time for the imaging should be no more than 6 hours.
- 3. MRI.** Magnetic resonance images (MRI) will be acquired to help in the analysis of the PET images. MRI scans will last about 1/2 hour and can be scheduled on a day separate from the PET scans.

**IMPORTANT INFORMATION: Participants will be asked to withhold their medication overnight (10-12 hours) before the PET scans. Clinical staff will be available to provide clinical care in the event of discomfort or an adverse event, and a neurologist will be available for immediate consultation by cellphone.**

During the period off medication, Parkinson symptoms will temporarily worsen. Participants are encouraged to tell their neurologist/doctor that they will be participating in this research, and that they will be withholding medication overnight. On the day of the scan, participants are also strongly encouraged to withdraw immediately from the study should they wish to resume medication. Participants may bring a care partner to accompany them for the duration of the scans. Participants are also asked to bring their medications with them so they can resume their normal medication routine after the scans. The research site will accommodate the person's need to wait until the medications take effect.

Incidental expenses such as travel to the PET centre, accommodation the night before each scan, underground parking at the centre, and meals directly related to scan or testing sessions will be provided or reimbursed by Centre for Addiction and Mental Health (CAMH).

### **How large is the study?**

The study expects to recruit 20 participants in each of three groups for a total of 60 participants.

**Has ethical approval been received for this research?**

Before participating in the study, volunteers should ask whether ethical approval has been given by the institute to conduct the research. The research will take place at the Vivian M. Rakoff PET Centre of CAMH in Toronto.

**How is the study funded?**

Research support comes from Parkinson Society Canada, Ontario Mental Health Foundation, and Canadian Institutes of Health Research.

**Who do I contact for more information?**

For more information, contact Isabelle Boileau, Ph.D., investigator, CAMH, 416-535-8501 ext 4918.

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