

RESEARCH TRIAL

Title of Trial

Investigational drug in Idiopathic Parkinson's Disease (IPD) With Cognitive Impairment, as Add-on to Dopamine Agonist and/or Levodopa (COGNITION)

What is Parkinson's disease ?

Parkinson's disease is a disorder of the brain. Movements are 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 disease nor stops it from advancing. (See Parkinson Society Canada's Information Sheet on *Progression of Parkinson's Disease* at www.parkinson.ca).

Parkinson's disease treatment

Since many of the motor symptoms of Parkinson's are the result of a lack of dopamine in the brain, most drugs work on the brain's complex chemistry and may need to be taken several times a day. As symptoms worsen over time, medications will need to be adjusted; perhaps taking them more frequently or at higher doses. A combination of drugs may be required to control symptoms.

For some people, non-motor symptoms of Parkinson's, like changes to cognitive ability, can be more bothersome than motor-symptoms. Sometimes adjusting the Parkinson's medications can control these symptoms; other times this approach may not work. It is important to find the right balance between the medication's benefits and side effects. (See Parkinson Society Canada's Information Sheet on *Parkinson's disease Medications: What you need to know!* at www.parkinson.ca)

What is being investigated?

This is a clinical trial to see whether an investigational drug¹ may be beneficial in treating a non-motor symptom of Parkinson's (e.g., cognitive changes). The objective of this trial is to evaluate whether the investigational drug, when taken with stable doses of dopamine agonist and/or levodopa, improves cognition in people living with Parkinson's.

What kind of trial is this?

This is a Phase 2 trial to test the effectiveness, safety and tolerability of the investigational drug. The study is a **randomized trial**, meaning that participants will be randomly assigned to two groups: one group will receive the investigational drug, the other group will receive an inactive drug (placebo) at a dose of 100mg/day. The trial is also **double blinded**, meaning that neither participants nor researchers will know which drug the participants receive. After 12 weeks, all participants will receive the investigational drug. After the trial has ended, participants may be eligible to continue taking the investigational drug as part of an open label study.

Who can participate?

The trial is looking for men and women between the ages of 45 to 80 years with a confirmed diagnosis of Parkinson's disease and who are experiencing changes in cognitive function. (Changes to cognitive function may include problems with planning, language, memory and/or attention span.) Participants should also be

receiving treatment for their Parkinson's symptoms with a stable dose of dopamine agonist and/or levodopa for at least 4 weeks.

What is required of the participants?

After randomly placed into one of the groups, participants will receive either the active drug or placebo for 12 weeks. After the initial 12 weeks, all participants will receive the active drug for 12 additional weeks. All participants will have periodic visits to the site clinic and they will be required to keep a daily trial log. The participant will also be assessed by the Parkinson's Disease Cognitive Rating Scale (PD-CRS) to compare cognitive functioning at the beginning of the trial and at 12 weeks.

How large is the trial?

The trial intends to enroll 100 participants throughout all of the participating countries. In Canada, the trial intends to enroll about 20 participants.

Have ethical standards been met?

This trial has been reviewed by all of the Ethics Committees of the participating sites, as well as by Health Canada. Participants must provide written informed consent prior to beginning the study.

Where are the sites in Canada?

The following chart indicates the Canadian locations, and contact information. For further information, please contact the sites directly. (The chart will be updated when/if more sites become available.)

Investigator	Institution	Location	Contact
Dr. Tilak Mendis	Parkinson's disease and Neurodegenerative Disorders Clinic	Ottawa, ON	(613) 737-4440 (Neila Mendis, Study Coordinator)
Dr. David King	Private Clinic	Halifax, NS	(902) 420-0296 (Vicky Newman, Study Coordinator)
Dr. Giovanna Pari	Kingston General Hospital	Kingston, ON	(613) 549-6666 ext 4293 (Adriana Breen, Study Coordinator)
Dr. Alex Rajput	Royal University Hospital	Saskatoon, SK	(306) 966 8009

¹The investigational drug is under clinical investigation in multiple clinical trials as an add-on therapy for the possible treatment of Parkinson's and has not been approved for use in the United States, Canada, Europe or elsewhere.

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