



**CLINICAL TRIAL:
Study seeks participants with Parkinson's
experiencing motor fluctuations**

Title of Trial

Investigational medication in Idiopathic Parkinson's Disease (IPD) With Motor Fluctuations, as Add-on to Levodopa (SETTLE).

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)

Parkinson's treatment

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.

When medication such as levodopa relieves symptoms, it is called being in an "on" state. This means a person can perform daily activities. When the medication is not working and the symptoms occur, the person is in an "off" state. The ideal state is controlling Parkinson's symptoms for longer periods during the day. (See Parkinson Society Canada's Information Sheet on Parkinson's Medications: What you need to know! at www.parkinson.ca)

What is being investigated?

The investigational medication is an inhibitor of MAO-B (Monoamine-Oxidase-B). MAO-B compounds enhance the effect of dopamine by preventing its breakdown. The investigational medication is being studied as a phase III trial to evaluate its effectiveness and safety as add-on therapy to a stable dose of levodopa. The study will measure the increased daily "on" time for a person with Parkinson's during an 18-hour diary-recording period.

What kind of study is this?

This study is randomised, meaning that participants will be randomly assigned to receive either the investigational active drug or an inactive drug (placebo); and double blinded, meaning that neither participants nor researchers will know the treatment being received. The objective of this study is to assess the effectiveness and safety of a dose range of 50 to 100 mg/day.

Who can participate?

The study is looking for men and women between the ages of 30 to 80 years with a confirmed diagnosis of Parkinson's of more than 5 years. Participants should also be receiving treatment for their Parkinson's symptoms with a stable dose of levodopa for at least 4 weeks.

What is required of the participants?

After randomization (treatment allocation), participants will undergo 24 weeks of treatment, with periodic visits to the doctor in-between. They will be required to keep a daily log.

How large is the study?

The study intends to enrol 484 participants throughout all the participating countries. In Canada, the study intends to enrol 20 participants.

Have ethical standards been met?

This study has been approved by all the Ethics Committees of the participating sites and by Health Canada.

Where are the sites in Canada?

The following chart indicates the Canadian locations, and contact information.

INVESTIGATOR	INSTITUTION	LOCATION	CONTACT
Dr. Anthony Dowell	Dynamic Clinical Research Group	Pointe Claire, QC	(514) 697-0439
Dr. Tilak Mendis	Parkinson's and Neurodegenerative Disorders Clinic	Ottawa, ON	(613) 737-4440
Dr. David King	Private Clinic	Halifax, NS	(902) 420-0296 (Vicky Newman, Study Coordinator)

For further information, please contact the sites directly.

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