

CLINICAL TRIAL

Title of the Research: Evaluation of efficacy and safety of an investigational drug in reducing moderate to severe L-dopa induced dyskinesias in patients with Parkinson’s disease.

What is Parkinson’s disease?

Parkinson’s is a neurodegenerative disease that affects approximately 100,000 Canadians. Movement is controlled by a chemical called dopamine. When cells that normally produce dopamine die, the symptoms of Parkinson’s appear. The most common symptoms are tremor, slowness and stiffness, impaired balance and rigid muscles. Other symptoms may include fatigue, soft speech, sleep disturbances, constipation, and cognitive changes. Currently there is no cure for Parkinson’s. Treatment helps with symptoms, but does not stop the underlying progression of the disease.

What treatment is available for Parkinson’s disease?

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.

Dyskinesias are involuntary, purposeless movements of any body part. They may be mild (slight ankle twisting) or severe (uncontrollable writhing movements). Dyskinesias are usually felt during the time a person with Parkinson’s has taken medications. See Parkinson Society Canada’s Information Sheet, *Parkinson’s Medications: What you need to know!* at www.parkinson.ca.

What is being investigated?

This Phase II study will evaluate the effectiveness and safety of an investigational drug in reducing moderate to severe dyskinesias in people living with Parkinson’s. This study takes place over a period of 13 weeks.

What kind of study is this?

This study is **randomized**, 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.

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. Participants should also be receiving treatment for their Parkinson’s symptoms with L-dopa, experiencing dyskinesias for at least three months.

The study is not open to anyone who has received surgical treatment for Parkinson’s; has had cancer within the past 5 years; or has an advanced, unstable disease (other than Parkinson’s).

How large is the study?

The study is seeking 234 participants in Canada, the United States, Australia, Finland, Germany, France, Italy, Spain and Japan.

Where are the sites in Canada?

The following chart lists sites currently recruiting in Canada.

City/Province	Centre/Institution	Contact
Quebec City, Quebec	Quebec Memory & Motor Skills Disorders Clinic	Emanuelle Pourcher, MD 418-692-2227
Ottawa, Ontario	Parkinson's and Neurodegenerative Disorders Clinic	Tilak Mendis, MD 613-562-435

Have ethical standards been met?

Participants should ask the study sites whether appropriate ethical protocols are in place.

What is required of the participants?

For more information visit www.clinicaltrials.gov or contact the study sites.

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