

Title of Trial

Famotidine for the treatment of levodopa-induced dyskinesia: An “N-of-1” Study

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. (See Parkinson Society Canada’s Information Sheet on *Progression of Parkinson’s Disease* at www.parkinson.ca)

How is Parkinson’s disease treated?

Current treatment neither cures Parkinson’s nor stops it from advancing. Since Parkinson’s is a degenerative 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 people with Parkinson’s may benefit from brain surgery (often known as deep brain stimulation). (See Parkinson Society Canada’s Information Sheet on *Parkinson’s Medications: What you need to know!* at www.parkinson.ca)

Why is this trial important?

A common treatment for Parkinson’s is levodopa, which is converted into dopamine in the brain and stored in nerve cells to replace depleted dopamine. It can help improve muscle rigidity and movement. Side effects of the medication include dyskinesias (involuntary movements). Other drugs can be prescribed to treat dyskinesias, however, side effects and lack of effectiveness often complicate their use.

It is important to reduce dyskinesias as they are a significant source of disability for people living with Parkinson’s.

What is being investigated?

The mechanism by which dyskinesias develop may involve changes in a number of non-dopamine pathways in the brain. One system that plays an important role in motor activity is the central histaminergic system. Histamine, a neurochemical, has a number of jobs within

the central nervous system including binding to receptors on brain cells to influence motor function. Blocking histaminergic receptors may reduce dyskinesias in Parkinson's.

Famotidine is a medication that targets the histaminergic system. It is currently approved to treat gastrointestinal disease. This will be the first study to assess the use of famotidine to treat levodopa-induced dyskinesias in people living with Parkinson's prior to undertaking a larger Phase II randomized controlled trial.

What kind of study is this?

This is an "N-of-1" trial, which means that each participant spends a period of time doing each of the possible treatments. Each participant will be given a randomized order for four treatment phases, including three different famotidine dose phases and a placebo phase. Each phase will last 14 days. The study is "blinded" which means the participants will not know which treatment they are receiving during each phase. The participants will be assessed using several rating scales, such as the Unified Dyskinesia Rating Scale, Clinical Global Impression Scale, and Lang-Fahn Activities of Daily Living Dyskinesia Scale.

Who can participate in the study?

The study is seeking participants who meet the following criteria:

1. Men and women diagnosed with Parkinson's disease who are under 80 years of age.
2. Those with a stable Parkinson drug routine for at least one month prior to enrollment in the study.
3. Those who experience dyskinesias which are bothersome or challenging in their daily lives.

Note: There are reasons why individuals may not be able to participate in the study (exclusion criteria) and these will be reviewed before a participant is accepted into the trial.

What is required of the participants?

Each participant will undergo a comprehensive baseline screening visit lasting approximately 2 hours. The participant will then return for a total of 10 study visits over 12-14 weeks, each approximately 1 hour in duration. At each visit, the participant will complete questionnaires to rate their dyskinesia severity, onset of effect of the treatment, and adverse side effects. The researcher will also assess dyskinesia severity and disability related to the person's Parkinson's disease.

How large is the study?

The study is seeking 12 participants.

Have ethical standards been met?

Yes. The study has been approved by the Research Ethics Board at the University Health Network in Toronto, Ontario, Canada.

How is the study funded?

Funding for the study has been provided by Parkinson Society Canada and The Michael J Fox Foundation for Parkinson’s Research.

Where are the sites in Canada?

Currently there is one site in Ontario.

Investigator	Institution	Location	Contact
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For further information, please contact the site directly.

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