

How can I learn more about STEADY-PD?

It's easy!

If you think you might want to participate in the STEADY-PD study, you can contact your local study research team.

You can also contact the PSG directly by calling our toll-free number:

1 (888) 887-3774 or visit us on the web at: www.Parkinson-Study-Group.org.

Your Local Study Coordinator:

Kathie Smith, RN
The Parkinson's Institute
(408) 734-2800

About the Parkinson Study Group

The Parkinson Study Group (PSG) is a non-profit group of physicians and other health care providers from medical centers in the United States and Canada, experienced in the care of Parkinson patients and dedicated to clinical research of Parkinson Disease. The PSG was formed in 1986, prompted by the recognition that clinical research in Parkinson Disease (PD) required the participation of large numbers of research patients (subjects) under the cooperative care of skilled and experienced research physicians.

The PSG aims to advance knowledge about the cause (s), disease progression and treatment of PD and related disorders. The PSG is committed to:

- open communication within the scientific community;
- ensuring research is fully reviewed by other health care providers prior to publication to make certain that all research results (good and bad) are available to the public;
- revealing all potential conflicts of interest of the group and each PSG member ,and;
- democratic governance of its organizations and activities.

STEADY PD Steering Committee

Tanya Simuni, MD
Principal Investigator

Kevin Biglan, MD, MPH
Dalton James Surmeier, PhD
Co-Principal Investigators

George Bakris
Robert Hauser
Jeana Jaglin
Anthony Lang
David Oakes
Bernard Ravina

STEADY-PD



*Safety, Tolerability, and
Efficacy Assessment of
Dynacirc® CR for PD*

PSG
PARKINSON STUDY GROUP

A clinical trial conducted by the PSG under a research grant award from the Michael J. Fox Foundation (MJFF) and the Dixon Foundation

About Clinical Trials

What is a clinical trial?

A clinical trial is a study to evaluate promising experimental treatments. They are designed to learn if new medications are safe, tolerable and effective. A clinical trial differs from an observational study, in which people are examined over time without receiving any experimental drugs or treatments.

What is the STEADY-PD study?

The Parkinson Study Group (PSG) is conducting a study of the research medication isradipine CR in persons who have a recent diagnosis of Parkinson disease (PD). Isradipine CR is a medication that is approved for the treatment of high blood pressure by the Food and Drug Administration Agency (FDA), but not for the treatment of PD. STEADY-PD is designed to determine general safety, tolerability and pilot data on the potential effective dose of isradipine CR on slowing the progression of PD.

Approximately 18 research centers across North America will enroll up to 100 subjects for 12 months each.

This study is under a research grant award from the Michael J. Fox Foundation (MJFF) and the Northwestern Dixon Foundation.

The 'who' and 'what' of STEADY-PD

Who can participate in STEADY-PD?

In order to qualify for participation in the STEADY-PD study, you must:

- *Have a diagnosis of PD of less than 3 years*
- *Be over 30 years old at the time of diagnosis*
- *Be able to provide written informed consent*
- *Be able to take oral medication and be willing to comply with study-specific procedures*
- *Not be taking dopaminergic therapy or projected to require therapy*
- *Not be pregnant, lactating or intend to become pregnant*

Further restrictions on participation will be provided to you by your local study research team.

What are the study procedures?

If you are interested in participating in the STEADY-PD study, you will first have a visit with the study doctor to determine if you are eligible to participate. If you qualify, then you will have a second visit to evaluate your general

health, mood and movement. Blood samples will be taken at specific visits.

During the study you will be assigned randomly to receive either one of three dosages of active study drug, or a pill that looks like the study drug but has no active ingredients. You will continue to take the study drug or placebo for a total of 52 weeks. Your total participation time will be 56 weeks. There are 12 visits scheduled for this study to evaluate your general health, mood, movement ability to tolerate the study drug.

What are the risks associated with participation in STEADY-PD?

There are mild risks associated with taking blood samples that include pain or bruising at the site where the blood is taken. Some of the side effects noted for this medication are chest pain, fast or slow heart beat, dizziness and shortness of breath. Further detail on these risks is explained in the consent form. Please ask your local study research team if you have any questions or concerns.

What are the benefits to me if I decide to participate in STEADY-PD?

While there may be no direct benefit to you from participating in the STEADY-PD study, you may be contributing to the growing knowledge about Parkinson Disease.