Clinical Coordination Center for STEADY-PD3

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Principal Investigators

SIMUNI, TANYA SIMUNI

Institution

NORTHWESTERN UNIVERSITY AT CHICAGO

Contact information of lead PI
Country

USA

Title of project or programme

Clinical Coordination Center for STEADY-PD3

Source of funding information

NIH (NINDS)

Total sum awarded (Euro)

€ 11,952,808.26

Start date of award

01/04/2014

Total duration of award in years

3

The project/programme is most relevant to:

Parkinson's disease & PD-related disorders

Keywords

Isradipine, Parkinson Disease, Futility, Dihydropyridines, disability

Research Abstract

DESCRIPTION (provided by applicant): The study objective is to establish the efficacy of isradipine 10 mg daily to slow the progression of Parkinson’s disease (PD) disability. This is a companion application to that of Kevin Biglan, MD, from the University of Rochester entitled “”Data Coordination Center for STEADY-PD3?”. PD is the second most common neurodegenerative disease that affects 1% of the population above the age 65. The principal

motor symptoms of PD are attributable to the preferential loss of dopaminergic neurons in the substantia nigra pars compacta. Recent data demonstrated that the selective vulnerability of these neurons may be due to the reliance of these neurons on L-type Cav1.3 Ca2+ channels and, more importantly for PD, that blocking these channels with israpadine, a dihydropyridine Ca2+ channel antagonist, protects these neurons in in vitro and in vivo models of Parkinsonism. Recent epidemiological data also points to a reduced risk of PD with chronic use of dihydropyridines. Isradipine is an approved agent for the treatment of hypertension. Our Phase II clinical studies have found that isradipine is safe and tolerable at the daily dose of 10 mg or below in participants with early PD. Isradipine penetrates the blood brain barrier and 10 mg daily dose achieves serum concentrations within the range found to be neuroprotective in animal models of PD. Based on these observations we propose to conduct a 36 month Phase 3 parallel group placebo controlled study of efficacy of isradipine 10mg daily versus placebo to slow the progression of PD disability in 336 participants with early PD. The study will include interim futility analysis thus eliminating the need to complete a standalone futility study. The proposed study is designed to address two specific aims. First, to establish the efficacy of isradipine 10 mg daily to slow the progression of PD disability as measured by the change in the Unified Parkinson Disease Rating Scale (UPDRS) Part I-III score over 36 months. Second, to ascertain effect of isradipine 10 mg daily on the progression of PD over 36 months as measured by a number of clinically meaningful and widely accepted measures of progression of disability in early PD including:1) Time to initiation and dose utilization of dopaminergic therapy; 2) Time to onset of dopaminergic motor complications; 3) Change in non-motor disability; Exploratory measures will include global measures of functional disability, quality of life, the change in the ambulatory capacity (sum of 5 UPDRS items: falling, freezing, walking, gait, postural stability) and cognitive function. The proposed study design represents a unique opportunity to evaluate the impact of a novel therapy to slow progression of PD disability and to determine if efficacy if such exists is associated with clinically meaningful benefits. The simple study design reflecting “”real life”” scenario and availability of low cost generic isradipine will facilitate the translatio of the study results, if positive, into a meaningful clinical application.

Lay Summary
PUBLIC HEALTH RELEVANCE: This is a Phase 3 study to establish the efficacy of isradipine 10 mg daily to slow the progression of Parkinson’s disease (PD) disability. If successful, this work will have a major impact on patient’s quality of life and public health as it will slow progression of PD related disability and thus reduce PD related health care costs. Thus identifying isradipine as a means for slowing the progression of PD disability would mark a significant breakthrough in PD therapeutics and would have a significant public health and economic impact.

Further information available at:

Types:
Investments > €500k

Member States:
United States of America

Diseases:
Parkinson's disease & PD-related disorders

Years:

2016

Database Categories:
N/A

Database Tags:
N/A