

# A Study to Assess the Clinical Effect of Droxidopa in the Treatment of Symptomatic Neurogenic Orthostatic Hypotension in Participants with Parkinson's Disease

**Official Study Title:** Phase 3: A multi-center, double-blind, **DOUBLE-BLIND** randomized, Parallel-Group, Placebo-Controlled study to assess the clinical **CLINICAL** effect of droxidopa in the treatment of Symptomatic Neurogenic Orthostatic Hypotension in Patients with Parkinson's disease

**Sponsor:** Chelsea Therapeutics

**Clinicaltrials.gov ID:** NCT01176240

**Study ID:** NOH306

## *Summary*

This is a study to evaluate the effects of an investigational drug, **INVESTIGATIONAL DRUG** Droxidopa, in participants with neurogenic orthostatic hypotension, a condition associated with Parkinson's disease **PARKINSON'S DISEASE** (PD) that causes a person's blood pressure to fall when they stand up. The study duration is approximately 14 weeks including up to two weeks for screening, **SCREENING** up to two weeks for proper dose finding, followed by an eight week treatment period and a follow-up visit after two weeks. An extension study is also available to continue treatment if determined appropriate by the study doctor.

Droxidopa is being studied to determine the effects on blood pressure changes upon standing up (orthostatic challenge). Symptoms and activity measurements will be evaluated to determine the effectiveness **EFFECTIVENESS** of the study drug.

## *Time Commitment*

- Less than six months
- Between eight and 13 study visits over 14 weeks. The visits will include a Screening Visit followed by a Baseline visit within two weeks, then between one and six daily visits to find the appropriate dose of study medication. After the appropriate dose is identified then there will be visits scheduled after one, two, four, and eight weeks (a follow-up visit may occur after 10 weeks if appropriate). An extension study is also available to continue treatment if it is determined appropriate by the study doctor.

## *Eligibility*

- **Minimum Age:** 18
- **Gender(s) Accepted:** Either

## *Inclusion Criteria*

- Clinical diagnosis of Parkinson's disease
- Clinical diagnosis of symptomatic neurogenic orthostatic hypotension

## *Exclusion Criteria*

- Use of vasoconstricting (blood vessel narrowing) agents for the purpose of increasing blood pressure;  
- Participants taking vasoconstricting agents such as ephedrine, dihydroergotamine, or midodrine must stop taking these drugs for at least two days prior to their baseline visit (Visit 2) and throughout the duration of the study
- Use of medication for the treatment of essential hypertension (high blood pressure with no identifiable cause)

- Have changed dose, frequency or type of prescribed medication, within two weeks of baseline visit (Visit 2) with the following exceptions:
  - Vasoconstricting agents such as ephedrine, dihydroergotamine, or midodrine
  - Short courses (less than two weeks) of medications or treatments that do not interfere with, or exacerbate the participant's condition under study (e.g. antibiotics)
- Alcohol or substance abuse within the past 12 months
- Women who are pregnant or breastfeeding
- Women of child bearing potential who are not using at least one method of contraception with her partner
- Male participants who are sexually active with a woman of child bearing potential and not using at least one method of contraception
- Untreated closed angle glaucoma
- Sustained severe high blood pressure
- Any significant uncontrolled cardiac arrhythmia (abnormal electrical activity in the heart)
- History of heart attack (myocardial infarction), or current unstable angina (chest pain caused by decreased blood flow to the heart muscle)
- Congestive heart failure
- Some types of diabetes and diabetic neuropathy
- History of some types of cancer within the past two years other than certain types of a successfully treated, non-invasive skin and non-invasive cervical cancer.
- Gastrointestinal condition
- Any major surgical procedure within 30 days of the baseline visit (Visit 2)
- Previously treated with droxidopa
- Currently receiving any investigational drug or have received an investigational drug within 30 days of the baseline visit (Visit 2)

### ***Enrollment***

**Expected Enrollment:** 84 (US)

**Date Enrollment Began:** Jun 2010

**Date Enrollment Ends:** Sep 2010

**Last Updated Date:** Aug 19 2010

**Trial Post Date:** Aug 11 2010

**Website:** [www.advancemed.info](http://www.advancemed.info) & <http://www.chelseatherapeutics.com/pipeline/droxidopa/indications.html>