SURE-PD3

A randomized, double-blind, placebo-controlled trial of urate-elevating inosine treatment to slow clinical decline in early Parkinson's disease

Clinical Trial Status:
This study will begin recruiting participants in May 2016

Clinical Trial Principal Investigator:
Dr. James Boyd

Clinical Trial Protocol Description:
The main objective of this study is to determine if oral inosine will slow the clinical decline in early PD, with a 2-year treatment dose that moderately elevates serum urate. We will also be assessing the safety and tolerability of this urate-elevating inosine treatment, as well as the long-term effects on non-motor symptoms, quality of life measures, and the need for dopaminergic medication changes.

Previous studies have shown increased urate levels to be associated with slower rates of PD progression. Urate is now being considered as a neuroprotective agent for PD, and the study drug, inosine, will be used to bring urate levels up to a moderate level. The Phase 2 study, SURE-PD, provided data which showed inosine to be safe, tolerable, and capable of elevating urate levels in early PD patients. This Phase 3 study hopes to further our understanding of the effects of inosine treatment and PD progression.

After we determine if a patient is eligible to participate, he/she will be randomly assigned in a 1:1 ratio to oral placebo or inosine capsules. Follow-up evaluations will occur in clinic at weeks 3, 6, 12, and months 6, 9, 12, 15, 18, 21 and 24. There will be a 3-month period where participants "wash out", or are not taking the study drug, and a final in-person evaluation will take place at month 27.

Clinical Trial Eligibility Criteria:
In order to participate you must meet the following criteria:

- Have a clinical diagnosis of idiopathic PD
    - PD diagnosis made within 3 years prior to first visit (screening visit)
- Are at least 30 years of age
- Are not requiring dopaminergic therapy
- Have non-fasting serum urate ≤ 5.7 mg/dL at first visit (screening visit)
- Have a Hoehn and Yahr stage 1.0-2.5
- If female, you must be using a reliable form of contraception, or be surgically sterile, or be postmenopausal

You will not be eligible to participate if any of the following criteria apply to you:

- Have any form of atypical parkinsonism
- Have a dopamine transporter brain scan without evidence of dopamine deficit
- Have a history of gout
- Have a history of uric acid or urate urolithiasis, or recurrent urolithiasis
- Have a history of myocardial infarction or stroke
- Have a history of chronic obstructive pulmonary disease

- Are taking inosine, allopurinol, febuxostat, probenecid, more than 50 IU of vitamin E daily, or more than 300 mg of vitamin C daily (though a daily standard multivitamin such as Bayer One-A-Day® or Centrum® is permissible), reserpine, methylphenidate, amphetamines, cinnarizine, monoamine oxidase-A inhibitors, tetrabenazine, neuroleptics or other dopamine blocking drugs
- Have had a change within 90 days prior to screening to a MAO-B inhibitor
- Are taking any anti-parkinsonian medications, other than MAO-B inhibitors

Note: this is a partial list of the inclusion and exclusion criteria

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