

NET-PD Newsletter



This newsletter is especially for NET-PD LS1 participants and their families
NET-PD . . . Exploring Options to Slow the Progression of Parkinson Disease

NET-PD LS1 Study Update

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The NET PD LS-1 study recruited a total of 1,741 people with Parkinson disease (PD) into the study which began in 2007. The study is slated to complete between June 2014 and May 2015 when all subjects will have a final in-person visit. We thank you for sticking with us and hope you continue to be committed to the study! At the study conclusion in 2015 we will achieve our goal and know whether taking creatine slows the progression of the symptoms and disability associated with Parkinson disease.

We would like to be sure you are aware that the study staff will work with you to accommodate your schedule. If something comes up unexpectedly, and you need to

cancel or change your appointment date or time, please let the site staff know and they will make every effort to reschedule, either early or later. Your continued participation is critical to our ability to determine if creatine is a compliment to the current medications to manage PD.

From a pure data collection perspective, there is nothing like an in-person visit, and this remains our preference. However, study visits have become more flexible in nature and if an in-person visit is not feasible we offer phone visits. Please take into consideration your circumstance and work with your study staff to continue to participate to the fullest extent possible.

Inside this issue:

<i>Publications</i>	2
<i>Diet in PD</i>	2
<i>Literary Corner</i>	3

Interim Analysis - What is it and what we hope to learn?

The study team has been hearing from our site coordinators that study fatigue is setting in. Participants are tired of taking study drug especially when they don't know if it works or not. Built into the study was an interim analysis. The purpose of the analyses is three fold. First and foremost is to review the safety profile (in addition to ongoing reviews by a separate body that is charged with this), secondly to look at whether the drug works so well that we should consider stopping the study as it currently exists and lastly to determine if taking the drug may not be effective in the longer term. This review occurred at the end of November. We will apprise you of the results via this Newsletter and we hope to have another participant conference call. Study staff at your center will let you know when this will be and how to join in the call. We anticipate this will be in January or February 2013.

Publications from the LS-1 study



You've been published!! Thanks to your contribution to the study, staff has published the Baseline results of the LS-1 study! The publication is in the *Movement Disorders Journal* ([Movement Disorders](#) 2012 Oct;27(12):1513-1521).

Below is the 'abstract' portion of the manuscript. An abstract provides a quick overview of the findings in the manuscript.

Based on the preclinical data and the results of a phase 2 futility study, creatine was selected for an efficacy trial in Parkinson's disease (PD). We present the design rationale and a description of the study cohort at baseline. A randomized, multicenter, double-blind, parallel group, placebo controlled Phase 3 study of creatine (10 g daily) in participants with early, treated PD, the Long-term Study – 1 (LS-1) is being conducted by the National Institute of Neurological Disorders and Stroke Exploratory Trials in Parkinson's Disease network.

The study utilizes a global statistical test (GST) encompassing five clinical rating scales to provide a multidimensional assessment of disease progression. A total of 1,741 PD participants from 45 sites in the United States and Canada were randomized 1:1 to either 10 g of creatine/day or matching placebo. Participants are being evaluated for a minimum of 5 years. The LS-1 baseline cohort includes participants treated with dopaminergic therapy and generally mild PD. LS-1 represents the largest cohort of patients with early treated PD ever enrolled in a clinical trial. The GST approach should provide high power to test the hypothesis that daily administration of creatine (10g/day) is more effective than placebo in slowing clinical decline in PD between baseline and the 5 year follow-up visit against the background of dopaminergic therapy and best PD care.



Diet in PD

In general everyone should eat a diet rich in fruits and vegetables and people with Parkinson disease are no different. However, given the side effects associated with some medications used to treat PD, and the fact that constipation often is an ongoing issue in PD, maintaining a diet rich in nutrients and an adequate fluid intake is even more important.

“Striving for five” is a mantra of a Rochester based food chain, Wegman's Market. Individuals are encouraged to eat five servings a day of fruit and vegetables. This will help with your fiber intake as well. Give it a try; it's a worthwhile lifestyle change!

Fluid intake is important to your health and well being. Set your goal high and try for 8 glasses (8 ounces each) daily. To avoid nighttime trips to the bathroom and sleep disruption, limit your fluid intake after 7 PM.

A diet rich in protein is important as well. According to WebMD the average adult man needs 56 grams of protein a day and the woman needs 46 grams per day. Protein is found in meats, dairy, eggs, grains, and soy to name but a few. Although infrequent some people with PD find that protein interferes with their carbidopa/levodopa absorption making it less effective. This can be lessened by separating your medication and food intake by at least 1-2 hours.

Literary Corner

The literary corner is dedicated to publishing articles, poems and other snippets from people with Parkinson disease. Some entries are from study participants, others are not.

We thank participant 10238 from Portland, Oregon for the following entry.

Parkinson's disease is not a choice, but quality of life is.

Following my diagnosis with Parkinson's disease, I frankly did not deal very well with the fact that I had this strange and incurable malady. I did not know anyone with Parkinson's and struggled with denial, depression, and anger and felt I would have to deal with this situation all by myself. I certainly could not tell friends and family.

Fortunately, on the advice of my physicians, I decided to become involved in a clinical trial, the NET-PD study. Through my involvement in this study I have met many individuals who are totally dedicated to helping their patients and so knowledgeable about resources, support groups, research, clinical studies and educational opportunities. They just plain cared and proved time and again that I was not alone in dealing with my Parkinson's.

Last year, I decided to participate in the Sole Support for Parkinson's walk, a fundraiser organized by Parkinson's Resources of Oregon, to let family and friends know about the event and to provide a little financial assistance.

I was just overwhelmed with the number of family (some came from California with their entire families including infants) and friends who made very generous contributions beyond the base registration fee. Without my asking, they packed up their children, traveled to Portland and made the walk in what was not very good weather.

Their support is something I will always remember and brings tears to my eyes to this day. I now have absolutely no doubt that I am not alone in any way and am so grateful to have been exposed to the Parkinson's resources available in Oregon.





Unfolding

by M. Moylan

Medical research will unfold

as a butterfly

emerging from the chrysalis

Painfully slow

Complicated

Cumbersome

Painstaking

but

Worth the wait

as we behold

the graceful creature

wing its way across the sky:

Successful maiden flight

