

USF Byrd Parkinson's Disease & Movement Disorders Center



813-396-0751

October 2012

USF Awarded National Parkinson Foundation Center of Excellence in the Center's new home



Dr. Robert Hauser, Medical Director

Dr. Peter Schmidt, NPF Foundation

In January of 2012, the Center moved from the South Tampa location at Harbourside Medical Tower into our current state of the art research and patient care facility located on the top floor of the USF Health Byrd Institute on campus. With over 5600 sq. feet, the Center is designed to provide exceptional clinical care and offers patients the option of participating in clinical trials that are essential to developing new treatments and possible cures.

The Center's goals dovetail with those set forth by the University of South Florida: Research and Scientific Discovery, including the generation, dissemination, and translation of new knowledge across disciplines; building sustainable healthy communities, embracing innovation, and supporting scholarly and artistic engagement.

The research performed at the Center is cutting edge; every new Parkinson's drug from Mirapex to Azilect has been tested at the USF Parkinson's Center. Most recently Dr. Hauser has been working with Impax Pharmaceuticals to develop Rytary, a new medication for Parkinson's Disease. See page 5 for details!



Upcoming Events:

Friday, November 9, 2012: PD: Education Council Event. Patient and Caregiver Regional Colloquia.

Tuesday November 13, 2012. Free Tremor Screening Day. Call (813) 396-0751 to reserve your spot.

Saturday, February 2, 2013: Annual Patient Care Symposium

For more information on upcoming events, please contact Eden Feldman: Efeldman@health.usf.edu



Patient Education Event

Parkinson's Disease Education Council
Patients and Caregivers Regional Colloquia

If you or someone you help care for is affected by Parkinson's disease (PD), we invite you to join the discussion of what's new in treatment options and support services. Presentations and discussions are led by physicians who specialize in the treatment of PD. The meeting will provide an opportunity to share your experiences with others affected by this condition.

Friday November 9, 2012

9:00am-11:30am

Location:

Hilton Tampa Airport Westshore
2225 North Lois Avenue
Tampa, FL 33607
(813) 877-6688

A complimentary light breakfast will be included.

Featured Speakers:

Robert A. Hauser, MD, MBA

Professor of Neurology, Molecular Pharmacology, and Physiology
Director, USF Byrd Parkinson's Disease and Movement Disorders Center
USF Health Byrd Institute
Tampa, FL

Claire Henchcliffe, MD, DPhil

Associate Professor of Neurology and Neuroscience
Director of the Parkinson's Institute at the New York-Presbyterian Hospital
Weill Cornell Medical Center
New York, NY

Registration

There are two ways to register for this program,

1. Online at www.mededreg.com. The invitation code for the program is **AZLHLXRC12**.
2. Call 800-308-8834 and reference invitation code **AZLHLXRC12**.

Importance of Medication Adherence in Parkinson's Disease

Sherrie Gould MSN, NP-C
Scripps Clinic Movement Disorders Clinic

Parkinson's is a progressive neurodegenerative disease that affects 1-2 out of every 1000 people in the United States. It is known to be a disorder that most commonly affects those over the age of 65 with 3 percent of this population being affected (1). The classic motor symptoms of Parkinson's disease are rigidity, tremor, bradykinesia (slowness) and postural instability (balance). PD symptoms are caused by a gradual loss of dopaminergic neurons in the brain resulting in significant disability. The mainstay treatment for this disease is medication aimed at supplementing dopaminergic activity in and around the basal ganglia. Clinical management of Parkinson's disease is dependent on taking medications at specific times throughout the day thereby allowing dopamine supplementation to be as consistent as possible during the waking hours. Levodopa which is the "gold standard" for Parkinson's has a short half-life of approximately 2 hours which complicates and intensifies the need for frequent dosing throughout the day.

In a retrospective analysis of patients with PD (1) 29,682 patients diagnosed with Parkinson's who received a new PD drug were analyzed. It was found that only 53.5% had compliance rates greater than 80% and 46.5% were noncompliant (compliance rate less than 80%). The study also found that patients who were on monotherapy with Rasagiline (an MAO-B inhibitor, dosed once daily) were significantly higher than those individuals taking carbidopa/levodopa or carbidopa/levodopa/entacapone, selegiline, pramipexole or ropinerole (all dosed more than once daily). The clinical implications for noncompliance are significant for the clinician as medication adjustments are made on patient report of PD symptoms which can vary widely

if medication schedule is not adhered to in a precise manner.

Symptomatic therapy is influenced by a variety of factors including the patient's age (younger the patient, the poorer the compliance), their quality of life factors including productive employment, the presence of significant bradykinesia or gait disturbance and their personal philosophy regarding the use of drugs (2). Poor compliance is associated with ignorance about the importance of taking meds on time, the cost of medication, trying alternative therapies, side effects of drugs, fear that a possible decrease in their medication will worsen their condition, and the complication of needing multiple daily dosing making compliance difficult(3). Complications of noncompliance include psychiatric problems, an increase in motor complications if dopaminergic drugs are overused, an interruption of consistent flow of dopamine to the brain leading to irregular control of symptoms and an increase in the incidence of "off time" that can persist for hours.

When discussing levodopa therapy in regards to meals there are a couple of considerations. Firstly, competition of other amino acids in the diet can interfere with transport of levodopa across both the intestinal mucosa and the blood brain barrier thereby reducing concentrations of L-dopa in the brain (4). This problem can be alleviated by having the patient take the medication 20 to 30 minutes prior to a meal or deferring protein consumption to the evening meal. Secondly, consumption of a meal delays gastric emptying therefore limiting absorption of the medication from the jejunum and consequently lowering concentration levels of L-dopa in the blood.

Tips for medication compliance:

- Take it at the same time every day, this will reduce off time and increase "on" time. Remind your patient that L-Dopa has a

short half-life so doses equally spaced throughout the day increases effectiveness.

- Provide patients with detailed information about the importance of continuous dopaminergic blood and brain levels (5). The absolute necessity of taking medication at proper times and in their prescribed doses cannot be overemphasized.
- Associate the taking of medication with daily events, like brushing your teeth.
- Use reminder systems to help remember when to take the next dose. There are medication boxes that have built-in alarm systems that can be set to sound off at the right times. Patients can use cell phones, alarm clocks and all kinds of other memory aids.
- Technology can help without being an excessive burden. A few valuable links are <http://medication-reminders.com> or <https://www.pillphone.com/PillLogin.htm>
- Placing stickers or reminder notes on places such as a medicine cabinet or refrigerator. Some patients buy a small magnetized white board with dry-erase markers and list pills on the board, marking the board with each medication. Each day, the board is marked after taking the medication.

Allstate Teams up for Parkinson's Walk

On Friday, March 30, the USF Parkinson's disease Center teamed up with Allstate for their annual "Fight Back, Move Forward" walk to raise awareness for Parkinson's. Over 120 Allstate employees participated, raising over \$2700 for Outreach and research.

Before the walk began, two Parkinson's patients

who are also employees of Allstate explained the significance of the walk, stating "If you need a face of Parkinson's, here it is!"

Many thanks to the amazing people of Allstate for their generosity and dedication.

If you would like to help with fundraising or donate to support our center please call Jessica Battersby at 813-396-0765.



A New Medication for Parkinson's Disease

Robert A. Hauser, MD, MBA

Parkinson's Disease and Movement Disorders Center

Rytary is an investigational, extended release formulation of carbidopa/levodopa. It is manufactured as tablets filled with beads that contain carbidopa/levodopa that dissolve at various rates to allow absorption from the gut over a longer period of time than occurs with carbidopa/levodopa IR (Sinemet). Rytary is designed to achieve therapeutic levodopa levels as quickly as carbidopa/levodopa IR (Sinemet), but to maintain therapeutic levodopa levels for a significantly longer time (1). For patients who are experiencing motor fluctuations on carbidopa/levodopa IR (Sinemet), this translates to a longer duration of benefit from each administration of medication. There is also interest as to whether use of Rytary in early Parkinson's disease will decrease the development of dyskinesia compared to carbidopa/levodopa IR, although this has not yet been tested.

In a phase 3 clinical trial (2,3), patients with moderate to advanced Parkinson's disease and motor fluctuations on carbidopa/levodopa IR (Sinemet) were switched to Rytary and then the two medications were compared in a blinded fashion. Results demonstrated that Rytary administered an average of 3.6 times per day reduced mean daily OFF time by 1.18 hours more ($p < 0.001$) than carbidopa/levodopa IR (Sinemet) administered an average of 5.0 times per day. In addition, quality of life scores were significantly more improved with Rytary and 39% of patients treated with Rytary rated themselves as much or very much improved compared with 17% for carbidopa/levodopa IR ($p < 0.0001$). Rytary was well tolerated and troublesome dyskinesia was not significantly increased.

In another phase 3 trial in moderate to advanced Parkinson disease patients with motor fluctuations (2, 4), Rytary was compared to carbidopa/levodopa IR (Sinemet) plus entacapone (Comtan). In this study, Rytary administered an average of 3.5 times per day reduced OFF time 1.4 hours more ($p < 0.0001$) than carbidopa/levodopa IR (Sinemet) plus entacapone administered an average of 5.0 times per day. Rytary was also demonstrated to provide benefit in early Parkinson's disease compared to placebo. Higher daily dosages provided more benefit, but there were also more side effects with higher dosages, including nausea and headache. Therefore, results from this study suggest that a relatively low dose of Rytary (145 mg TID) might provide the best balance between efficacy and side effects for the treatment of early Parkinson's disease.

These studies suggest that patients with moderate to advanced Parkinson's disease who are experiencing motor fluctuations on carbidopa/levodopa IR (Sinemet) or carbidopa/levodopa IR (Sinemet) plus entacapone (Comtan) 4 or 5 times per day will likely be able to switch to Rytary 3 or 4 times per day and experience a reduction in OFF time. Patients taking carbidopa/levodopa IR (Sinemet) 3 times a day who begin to experience motor fluctuations can probably switch to Rytary 3 times per day and reduce or eliminate their OFF time. Rytary may also be useful as a bedtime medication to provide antiparkinsonian efficacy further into the night than carbidopa/levodopa IR (with or without entacapone). In early Parkinson's disease, there is interest in the possibility that using Rytary rather than carbidopa/levodopa IR (Sinemet) can smooth levodopa delivery and avoid fluctuating levels of levodopa to reduce the development of dyskinesia over time. However, this has not yet been tested and is currently theoretical.

Information regarding Rytary is currently being reviewed by the FDA and the medication may be available, if approved, early in 2013. You can read more about Rytary at the following website:

Press Ctrl and [Click Here](#)

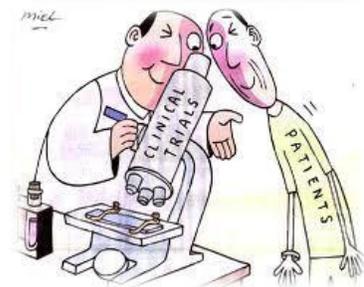
You can also read about [The Future Treatments for Parkinson's Disease](#): Press Ctrl and [Click Here](#)

Clinical Trial Participation

Without research, medicine would not have made the advances that we enjoy today. For you and for future patients, research is essential. By being part of a clinical trial, you can help move research forward. One of the most compelling reasons to participate in clinical research trials is the potential to help other people who also live with your condition. Not only are you becoming active in improving your own health, but you may also be enriching the health of people everywhere. You may contribute to a better understanding of your condition, which could lead to new or improved treatments. You might also make better treatments available for your future self!

All study-related care is provided at no charge, including:

- Physician visits and physical examinations
- Laboratory services
- Study medications



We are currently enrolling patients for the following movement disorders:

Early PD

Diagnosis of PD for 2 years or less on no treatment

Male or Female – 30 years or older

Length: 60 months (15 clinic visits)

Diagnosis of PD less than 5 years and on a stable dose of rasagiline or selegiline for at least 8 weeks but no more than 8 months.

Male or female – 30 years or older

Length: 44 weeks (6 clinic visits, 1 phone call)

Advanced PD

Diagnosis of PD with levodopa-induced dyskinesia. Subjects completing study may be eligible for open-label long term safety study to follow.

Male or female – 30 – 80 years

Length: 13 weeks (9 clinic visits)

Cervical Dystonia

Diagnosis of CD with less than 10 weeks of benefit from onabotulinumtoxinA treatment

Male or female – 18 – 81 years

Length: 30-32 months

We have several new clinical trials in the start-up phase and our center receives new trial information on an ongoing basis.

If you are interested in participating in a clinical trial please contact our **Research Administrator, Ms. Sherry Harlan, at 813 396-0768.**

Clinical Trials: Around Half of New Treatments Perform Better Than Existing Treatments, Review Finds ⁷

ScienceDaily, October 16, 2012

On average, new treatments perform better in clinical trials only slightly more often than existing treatments, according to a new systematic review published in The Cochrane Library. The fact that experimental treatments are not more effective may seem disappointing, but the authors of the review say their findings satisfy an important ethical requirement for clinical trials.

Randomized trials compare the effects of one treatment to another. In a randomized trial patients are randomly allocated to different treatment groups to ensure that like will be compared with like. When a new treatment is being tested, it is hoped or even expected that it will be better than the established treatment with which it is being compared. These expectations lead to an ethical dilemma. If the researchers already know that one treatment is better, they would be knowingly allocating some people to an inferior treatment. If randomized trials are to be ethical, therefore, only half of new treatments should turn out to be better than existing ones.

Cochrane researchers looked at evidence from 743 publicly funded randomized trials involving 297,744 patients in total. The trials included new, experimental treatments for cancer and neurological disorders, as well as a range of other diseases. On average, only very slightly more than half of new treatments proved to be better than established treatments.

The researchers found the same pattern in trials going back five decades. The results provide an answer to the question posed 15 years ago in the British Medical Journal by Iain Chalmers, a founder of the Cochrane Collaboration and one of the authors of the review. "In 1997, in a letter published in the BMJ, I asked 'What is the prior probability of a proposed new treatment being superior to established treatments?' I think this review currently provides the best answer to that question," said Chalmers.

To read the full article: Press Ctrl and [Link to Original](#)

"The results of this review are extremely encouraging," said Robert A. Hauser, MD. "They indicate that research does lead to better treatments, not all of the time, but frequently."

USF Byrd Parkinson's Disease & Movement Disorders Center

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Parkinson's Disease & Movement Disorders Center, Tampa FL

About Our Center

The University of South Florida's Byrd Parkinson's Disease & Movement Disorders Center is a large academic Center serving much of West and Central Florida including Hillsborough, Pasco, Hernando, Manatee, Sarasota, Pinellas, Polk and Orange Counties. The Program is

comprised of a highly active, nationally-recognized multi-disciplinary care team, and has a long history of clinical research and a strong commitment to community outreach.

Established in 1986 as a full-time specialty clinic to provide focused neurological care for

individuals with movement disorders, the mission of the Center is to advance knowledge and treatment of movement disorders. Our goals are to provide superior clinical care and to expand knowledge through research. We are currently accepting new patients.

We are currently accepting new patients.

Exercise Classes for Patients

Classes are free to patients and caregivers. They increase flexibility and help with balance. All fitness levels are welcome.

Please call:

(813) 396-0751

New Port Richey (Tai Chi)
The Cottages of Port Richey
5905 Pine Hill Dr.
Thursdays, 1-2 PM

South Tampa (chair yoga)
Grand Court of Tampa
4902 Bayshore Blvd.
Thursdays 1-2 PM

Clearwater (Tai Chi)
Horizon Bay
3141 N McMullen Booth Rd
Thursdays, 10:30-11:30

Temple Terrace (Tai Chi)
Sherwood Forest Center: Taoist Tai Chi
10919 N 56th Street
Mondays & Wednesdays, 12-1

Ruskin/Brandon (Tai Chi)
Taoist Tai Chi Society
911 Bryan Rd.
Monday, Wednesday, & Friday, 10:30-11:30

North Tampa (Tai Chi)
Carrollwood Cultural Center
4537 Lowell Rd.
Tuesdays, 12:30-1:30

Winter Haven (Tai Chi)
Main Street Dojo's Inc.
126 W Central Ave.
Tuesdays, 11:30-12:30

Sarasota (Chair fitness)
Horizon Bay
730 S Osprey Ave.
Thursdays, 2-3 PM

Spring Hill (Tai Chi)
Body Fitness
5181 Mariner Blvd.
Tuesdays, 2:30-3:30

Largo (Water Aerobics)
Cypress Palms
400 Lake Avenue NE
Wednesday, 10:30-11:30

Be part of the Unstoppable force working to cure Parkinson's disease!

Your gift will help provide vital resources for Parkinson's research, caregiver education and support here in Tampa Bay.

If you would like more information concerning funding opportunity please contact:
Jessica Battersby:
(813) 396-0765, jbatters@health.usf.edu.

All checks or money orders made payable to: **250028 USF Foundation, Inc.**

Please cut along line and mail in to:

USF Byrd Parkinson's Disease and Movement Disorders Center
Attn: Jessica Battersby
4001 E. Fletcher Avenue, 6th Floor
Tampa FL, 33613

Contact Information:

Firm/ Affiliation _____

Full Name _____

Address: _____

City _____

State _____

Zip Code _____

Email Address _____

Telephone _____

This gift is made in honor or memory (circle one) of:

I support PD Care and Research with a donation of:

\$50 \$100 \$500 \$1000 Other

Donations of \$1000 or more will receive a plaque with your message on our giving tree mounted in our office.

Message:

Gifts are a meaningful way to honor or remember a loved one with Parkinson's disease. We are extremely grateful for your interest and support in fighting Parkinson's disease.