Mild Cognitive Impairment in Parkinson's Disease

The recruitment status of this study is unknown because the information has not been verified recently.

Verified January 2012 by University of Pennsylvania.
Recruitment status was Recruiting

Sponsor:
University of Pennsylvania

Information provided by (Responsible Party):
University of Pennsylvania

ClinicalTrials.gov Identifier:
NCT01519271

First received: January 10, 2012
Last updated: December 17, 2013
Last verified: January 2012

Purpose

Mild cognitive impairment, including difficulty with solving problems, planning, attention, or recalling information, can be a significant problem for individuals with Parkinson's disease. Even mild cognitive difficulties can lead to worse functioning, quality of life, depression, and difficulty for caregivers. Thus, ideally treatment at this stage would improve both cognitive symptoms and some of the other problems associated with these symptoms.

Despite the fact that mild cognitive impairment is a serious problem for Parkinson's disease patients little is known about how best to treat it. This study is a 24-week clinical trial to see if a Food and Drug Administration (FDA)-approved drug, the Exelon (rivastigmine) Patch, is useful in treating mild cognitive impairment in patients with Parkinson's disease. Currently, the Exelon (rivastigmine) Patch is FDA-approved for the treatment of mild to moderate dementia in Alzheimer and Parkinson's disease patients.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
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<tbody>
<tr>
<td>Parkinson's Disease</td>
<td>Drug: Exelon Patch (rivastigmine transdermal system)</td>
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<tr>
<td>Mild Cognitive Impairment</td>
<td>Drug: Placebo Patches</td>
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Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Crossover Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A Phase IV Randomized, Double-Blind, Placebo-Controlled, Crossover Single Site Study Of Exelon® Patch (Rivastigmine Transdermal System) For Mild Cognitive Impairment In Parkinson's Disease

Resource links provided by NLM:

Genetics Home Reference related topics: Parkinson disease Perry syndrome

MedlinePlus related topics: Dementia Memory Mild Cognitive Impairment Parkinson's Disease

Drug Information available for: Rivastigmine Rivastigmine tartrate

U.S. FDA Resources

Further study details as provided by University of Pennsylvania:

Primary Outcome Measures:

- Alzheimer's Disease Cooperative Study- Clinical Global Impression Change (ADCS-CGIC) [ Time Frame: The ADCS-CGIC will be administered at baseline, week 4, week 10, week 14, week 18, and week 24. ] [ Designated as safety issue: No ]
The ADCS-CGIC is the most commonly used measure of global change in dementia psychopharmacology studies.

Secondary Outcome Measures:

- **Treatment Emergent Symptom Scale (TESS)** [Time Frame: The TESS be administered at week 4, week 10, week 14, week 18, and week 24.] [Designated as safety issue: Yes]
  We previously used a modified TESS to assess psychiatric, cognitive, and motor adverse effects in psychiatric treatment studies in Parkinson's Disease.

- **Montreal Cognitive Assessment (MoCA)** [Time Frame: The MoCA will be administered at baseline, week 10, week 14, and week 24.]
  [Designated as safety issue: No]
  The MoCA will be used as the global cognitive screening instrument.

- **Mind Streams Global Assessment Battery (GAB)** [Time Frame: The GAB will be administered at baseline, week 10, week 14, and week 24.]
  [Designated as safety issue: No]
  The GAB, which includes tests of memory, executive function, visual spatial function, verbal function, attention, information processing speed, and motor skills.

- **Clinical Dementia Rating (CDR)** [Time Frame: The CDR will be administered at baseline, week 10, week 14, and week 24.]
  [Designated as safety issue: No]
  The CDR will be used as an assessment of cognitive function and as a means of identifying potential participants with MCI.

- **Functional Activities Questionnaire (FAQ)** [Time Frame: The FAQ will be administered at baseline, week 10, week 14, and week 24.]
  [Designated as safety issue: No]
  The FAQ assesses Individual Activities of Daily Living (IADLs).

- **Assessment of Daily Function Questionnaire** [Time Frame: The Assessment of Daily Function Questionnaire will be administered at baseline, week 10, week 14, and week 24.]
  [Designated as safety issue: No]
  The Assessment of Daily Function Questionnaire is specific to cognitive impairment.

- **Parkinson Disease Questionnaire (PDQ-8)** [Time Frame: The PDQ-8 will be administered at baseline, week 10, week 14, and week 24.]
  [Designated as safety issue: No]
  The 8-item version of the PDQ-39 will serve as a disease-specific measure of health-related Quality of Life.

- **Gordon Diagnostic System (GDS)** [Time Frame: The GDS will be administered at baseline, week 10, week 14, and week 24.]
  [Designated as safety issue: No]
  Attentional impairment specifically is a strong predictor of the ability to perform Activities of Daily Living in Parkinson's Disease. Therefore, we will add the GDS as a specific measure of attention.

- **Dementia Rating Scale (DRS-2)** [Time Frame: The DRS-2 will be administered at baseline, week 10, week 14, and week 24.]
  [Designated as safety issue: No]
  The DRS-2 has been validated as an assessment instrument for Parkinson's Disease Dementia, discriminates between Parkinson's Disease-Mild Cognitive Impairment and Parkinson's Disease Dementia, predicts long-term conversion to Parkinson's Disease Dementia, and is sensitive to improvements in cognition and Activities of Daily Living function associated with treatment.

- **Psychiatric Measures** [Time Frame: These instruments will be administered at baseline, week 10, week 14, and week 24.]
  [Designated as safety issue: No]
  The 15-item Geriatric Depression Scale (GDS-15), State Anxiety Inventory (SAI), Apathy Scale, and a modified Parkinson's Psychosis Rating Scale (PPRS) will be used as measures of severity of psychiatric symptoms and to probe the impact of rivastigmine treatment on psychiatric symptoms that are frequently co-morbid with cognitive impairment in Parkinson's Disease.

- **Measures of Parkinson's Disease Severity** [Time Frame: The UPDRS will be administered at baseline, week 10, week 14, and week 24, and the Hoehn & Yahr stage and Schwab and England Scale will be administered at baseline only.]
  [Designated as safety issue: No]
  The UPDRS motor component (Part III) and the Hoehn & Yahr stage will be used as measures of disease severity. The Schwab and England will be used as a measure of Activities of Daily Living.

- **Everyday Cognition Battery (ECB) and Memory Acquisition-Transfer Task** [Time Frame: If time allows both measures will be administered at baseline, week 10, week 14, and week 24.]
  [Designated as safety issue: No]
The Everyday Cognition Battery will be administered as a performance-based measure of functional abilities. Likewise, the Memory Acquisition-Transfer Task, a computer-based measure of memory acquisition and transfer will be administered if time allows.

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<th>Arms</th>
<th>Assigned Interventions</th>
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| Placebo Comparator: Placebo Patch | Drug: Placebo Patches  
The placebo patches will appear identical to the medication patches however they will be inactive (they will not contain rivastigmine). |
| Active Comparator: Exelon Patch (rivastigmine transdermal system) | Drug: Exelon Patch (rivastigmine transdermal system)  
The Exelon Patch (rivastigmine transdermal system) is a Cholinesterase Inhibitor approved by the FDA to treat Alzheimer's and Parkinson's Disease Dementia.  
5-10cm² (4.6-9.5 mg of rivastigmine/24 hours) |

**Detailed Description:**
This study has 2 phases. Each phase will last 10 weeks and there will be a 4-week break between the 2 phases. Thus, you will be enrolled in the study for a total of 24 weeks. Over the course of the 24-week period we will schedule to see you in-person 6 times and check-in with you on the telephone 4 times, 2 times during each phase.

**Phase I**
Screening (may be the same day as the baseline visit) - Research personnel will determine if you are eligible to participate in this study.
Visit 1 - Baseline Visit, Start Study Medication
Phone Call 1 - Check in to see how you are feeling after starting the study medication
Visit 2 - 4 Weeks after Baseline, Increase Study Medication if tolerated
Phone Call 2 - Check in to see how you are feeling after increasing the study medication
Visit 3/Phase I Termination Visit - 10 Weeks after Baseline (Phase I Termination Visit)
4 Week Break (no study medication)

**Phase II**
Visit 4/Phase II Baseline - 14 Weeks after Baseline, Start Study Medication
Phone Call 3 - Check in to see how you are feeling after starting the study medication
Visit 5 - 18 Weeks after Baseline, Increase Study Medication
Phone Call 4 - Check in to see how you are feeling after increasing the study medication
Visit 6/Phase II and Study Termination Visit - 24 Weeks after Baseline
Visits 1, 3, 4, and 6 will last for about 2½ hours and visits 2 and 5 about 30 minutes. The ‘check in’ phone calls will last approximately 5-10 minutes.

After 24 weeks, your study participation will be over.

**Eligibility**

Ages Eligible for Study: 40 Years to 85 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

**Criteria**

**Inclusion Criteria:**
1. Participants must be experiencing symptoms of mild cognitive impairment; this will be determined by study personnel.
2. Participants must be on a stable medication regimen for 2 months prior to starting the study (necessary dose adjustments during the study are acceptable).
3. Participants are capable of giving informed consent supported by not meeting Parkinson's disease Dementia criteria; this will be determined by study personnel.

**Exclusion Criteria:**
1. Active suicide ideation.
2. Weighing less than 100 lbs (45 kgs).
4. Diagnosis of Dementia
5. Taking certain types of medications may be an exclusion criteria, this will be reviewed with all potential participants.
6. Females that are pregnant, planning to become pregnant, or are breastfeeding will not be included in the study. Females of childbearing potential will need to verify that they are not pregnant by a negative urine pregnancy test.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01519271

Contacts

Contact: Eugenia Mamikonyan, MS 215-615-3085 Eugenia.Mamikonyan@uphs.upenn.edu
Contact: Kimberly Papay, BS 215-349-8390 Kimberly.Papay@uphs.upenn.edu

Locations

United States, Pennsylvania

University of Pennsylvania, Ralston House
Philadelphia, Pennsylvania, United States, 19104
Contact: Eugenia Mamikonyan, MS 215-615-3085 Eugenia.Mamikonyan@uphs.upenn.edu
Contact: Kimberly Papay, BS 215-349-8390 Kimberly.Papay@uphs.upenn.edu

Sponsors and Collaborators

University of Pennsylvania

Investigators

Principal Investigator: Daniel Weintraub, MD University of Pennsylvania

More Information

No publications provided

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ClinicalTrials.gov Identifier: NCT01519271 History of Changes
Other Study ID Numbers: 813803
Study First Received: January 10, 2012
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Health Authority: United States: Institutional Review Board

Keywords provided by University of Pennsylvania:
Parkinson's Disease Attention
Mild Cognitive Impairment Exelon
Cognition Rivastigmine
Memory

Additional relevant MeSH terms:
Parkinson Disease Rivastigmine
Cognition Disorders Cholinesterase Inhibitors
Mild Cognitive Impairment Enzyme Inhibitors
Parkinsonian Disorders Molecular Mechanisms of Pharmacological Action
Basal Ganglia Diseases Pharmacologic Actions
Brain Diseases Cholinergic Agents
Central Nervous System Diseases Neurotransmitter Agents
Nervous System Diseases Physiological Effects of Drugs
Movement Disorders Neuroprotective Agents
Neurodegenerative Diseases Protective Agents