IMProving Executive Function Study (IMPRES)

This study is not yet open for participant recruitment. (see Contacts and Locations)

Verified June 2017 by University of Pennsylvania

Sponsor:
University of Pennsylvania

Information provided by (Responsible Party):
University of Pennsylvania

ClinicalTrials.gov Identifier:
NCT03187353

First received: June 12, 2017
Last updated: NA
Last verified: June 2017
History: No changes posted

Purpose

This is a double-blind, placebo-controlled, crossover study testing whether Vyvanse (lisdexamfetamine; LDX) improves executive functioning (EF) in 100 postmenopausal women who report onset of EF difficulties after oophorectomy. This study involves magnetic resonance imaging (MRI) to see how LDX affects brain chemistry while undergoing two 6-week trials of the study drug and placebo capsules.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cognitive Impairment RRSO</td>
<td>Drug: Lisdexamfetamine Drug: Placebo oral capsule</td>
<td>Phase 4</td>
</tr>
</tbody>
</table>

Study Type: Interventional

Study Design: Allocation: Randomized
Intervention Model: Crossover Assignment
Masking: Participant, Investigator, Outcomes Assessor
Primary Purpose: Treatment

Official Title: Multi-Modal Imaging of Psychostimulant Effects on Executive Function Post-RRSO

Resource links provided by NLM:
Drug Information available for: Lisdexamfetamine Lisdexamfetamine dimesylate

U.S. FDA Resources

Further study details as provided by University of Pennsylvania:

Primary Outcome Measures:
- Brown Attention Deficit Disorder Scale (BADDS) Score [ Time Frame: 6 weeks ]
  To subjectively determine whether treatment with LDX improves self-reported executive function (EF) via the BADDS

Secondary Outcome Measures:
- Brain activation [ Time Frame: 6 weeks ]
  To objectively determine the impact of LDX on executive system activation during a working memory task via proton magnetic resonance spectroscopy (1H-MRS) and functional magnetic resonance imaging (fMRI)

Estimated Enrollment: 100
Anticipated Study Start Date: July 1, 2017
Estimated Study Completion Date: July 1, 2022
Estimated Primary Completion Date: July 1, 2022 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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</thead>
<tbody>
<tr>
<td>Active Comparator: Lisdexamfetamine</td>
<td>Drug: Lisdexamfetamine Stimulant medications are used to reduce interruptive behavior, fidgeting, and other hyperactive symptoms, as well as help a person finish tasks and improve his or her relationships for adults who have ADHD. Please note that the FDA has not approved the use of Vyvanse® for the treatment of memory and concentration difficulties related to medically induced menopause. Other Name: Vyvanse</td>
</tr>
<tr>
<td>Participants will have a 50% chance of receiving the active study medication. They will begin at 20 mg/d and will increase up to 60 mg/d after 4 weeks, if well tolerated. Total time on the study drug is up to 6 weeks.</td>
<td></td>
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<tr>
<td>Placebo Comparator: Placebo</td>
<td>Drug: Placebo oral capsule The placebo capsule will be filled with microcellulose. Other Name: sugar pill</td>
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<tr>
<td>Participants will have a 50% chance of receiving the placebo for this study. They will begin with 1 sugar pill and will increase up to 3 pills after 4 weeks. Maximum time for taking the placebo is 6 weeks.</td>
<td></td>
</tr>
</tbody>
</table>
Detailed Description:

Following a medically induced menopause, many women report difficulty in remembering things, focusing and concentrating. The purpose of this study is to examine the effects of a stimulant medication called Vyvanse® (lisdexamfetamine; LDX) on executive functioning, such as attention, processing, organization, and memory, in women who are experiencing executive functioning difficulties after having undergone a risk-reducing bilateral salpingo-oophorectomy (RRSO). This study involves magnetic resonance imaging (MRI) to see how LDX affects brain chemistry while undergoing two 6-week trials of the study drug and placebo capsules.

Individuals wishing to participate in this study are medically healthy women between the ages of 35-55 years old who have undergone a risk-reducing bilateral salpingo-oophorectomy (RRSO) within the previous 15 years. Participants must have been premenopausal before undergoing RRSO (meaning they were having regular periods). They also must not have undergone radiation or chemotherapy at any point before or after your RRSO.

Furthermore, participants must not suffer from a mental illness, including Attention Deficit Hyperactivity Disorder (ADHD), and must not have a recent history of drug abuse. Additionally, participants must also be right-handed, not suffer from a fear of small, enclosed spaces (claustrophobia), and not have any implanted medical devices such as a pacemaker, orthodontic braces, or shrapnel. They must not have a history of seizures, uncontrolled hypertension or known renal impairment.

Eligibility

Ages Eligible for Study: 35 Years to 55 Years (Adult)
Sexes Eligible for Study: Female
Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:

- Female;
- Age 35-55;
- Have undergone risk-reducing bilateral salpingo-oophorectomy (RRSO) within the previous 15 years AND were premenopausal at the time of RRSO;
- Score of ≥ 20 on the Brown Attention Deficit Disorder Scale (BADDS);
- Onset of executive function difficulties occurred post RRSO;
- Right-handed;
- Are fluent in written and spoken English;
- Are able to give written informed consent (obtained at screening visit);
- Have an Intelligence Quotient of at least 90 as per the Wechsler Abbreviated Scale of Intelligence (WASI) assessment.

Exclusion criteria:

- Current, untreated psychiatric disorder;
- Substance use disorder within the previous 3 years;
- Lifetime history of ADHD or psychotic disorder including bipolar disorder, schizoaffective disorder, and schizophrenia;
• Lifetime history of stimulant abuse or dependence;
• Regular use of psychotropic medications except selective serotonin reuptake inhibitors (SSRI), serotonin noradrenergic reuptake inhibitors (SNRI), bupropion, zolpidem or gabapentin;
• Current use of aromatase inhibitors or chemotherapies (within the past year);
• Previous history of sensitivity or adverse reaction to lisdexamfetamine (LDX);
• History of seizures or unstable medical condition;
• Known heart disease or clinically significant abnormal electrocardiogram during screening as determined by the study MD; 10. Uncontrolled hypertension; 11. Presence of a metallic implant contraindicative to scanning at the 7T level; 11. Claustrophobia. 12. Consistent systolic blood pressure of >145mm Hg or diastolic blood pressure >90 mm Hg after three readings at time of screening; 13. Known renal impairment and End Stage Renal Disease (ESRD).

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: NCT03187353

Contacts

Contact: Emily A Lipner, BA 215-573-8873  lipnere@mail.med.upenn.edu
Contact: Claudia J Iannelli, MS 215-417-8839  sclaud@mail.med.upenn.edu

Locations

United States, Pennsylvania

Not yet recruiting

3535 Market Street  
Philadelphia, Pennsylvania, United States, 19104
Contact: Emily Lipner 215-573-8873  lipnere@mail.med.upenn.edu
Contact: Cynthia Neill Epperson, MD 215-573-8871  cepp@mail.med.upenn.edu

Sponsors and Collaborators
University of Pennsylvania

Investigators

Principal Investigator:  C. Neill Epperson, MD  University of Pennsylvania

More Information

Additional Information:
Research at the Penn Center for Women's Behavioral Wellness

Publications:

Responsible Party: University of Pennsylvania

ClinicalTrials.gov Identifier: NCT03187353

Other Study ID Numbers: 826981

Study First Received: June 12, 2017

Last Updated: June 12, 2017

Individual Participant Data

Plan to Share IPD: Undecided

Studies a U.S. FDA-regulated Drug Product: Yes
Studies a U.S. FDA-regulated Device Product: No
Product Manufactured in and Exported from the U.S.: No

Keywords provided by University of Pennsylvania:

Cognitive complaints Memory
RRSO Cognition
Oophorectomy Early menopause

Additional relevant MeSH terms:

Cognition Disorders Dopamine Uptake Inhibitors
Neurocognitive Disorders Neurotransmitter Uptake Inhibitors
Mental Disorders Membrane Transport Modulators
Lisdexamfetamine Dimesylate Molecular Mechanisms of Pharmacological Action
Central Nervous System Stimulants Dopamine Agents
Physiological Effects of Drugs Neurotransmitter Agents

ClinicalTrials.gov processed this record on June 14, 2017