Attention Deficit Hyperactivity Disorder (ADHD) Prediction of Treatment Response

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

Verified May 2017 by Massachusetts General Hospital

Sponsor:
Massachusetts General Hospital

Collaborator:
Massachusetts Institute of Technology

Information provided by ( Responsible Party):
Joseph Biederman, MD, Massachusetts General Hospital

ClinicalTrials.gov Identifier:
NCT03153488

First received: May 11, 2017
Last updated: NA
Last verified: May 2017
History: No changes posted

Purpose
This is a 6-month open-label, randomized control trial in adults to find out if certain neuromarkers can predict individual treatment response to stimulant medications for Attention Deficit Hyperactivity Disorder (ADHD). Males and females, ages 18-55, will be randomized to receive either an amphetamine or a methylphenidate formulation for their ADHD. Before beginning to receive medication treatment, each subject will complete an MRI scan at MIT.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attention Deficit Hyperactivity Disorder</td>
<td>Drug: Methylphenidate LA (Ritalin)</td>
<td>Phase 4</td>
</tr>
<tr>
<td></td>
<td>Drug: Mixed Amphetamine Salts XR (Adderall)</td>
<td></td>
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</table>

Study Type: Interventional

Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: No masking
Primary Purpose: Treatment
Official Title: Attention Deficit Hyperactivity Disorder (ADHD) Prediction of Treatment Response

Resource links provided by NLM:

MedlinePlus related topics: Attention Deficit Hyperactivity Disorder

Drug Information available for: Amphetamine sulfate Methylphenidate Methylphenidate hydrochloride Amphetamine Sodium chloride

U.S. FDA Resources

Further study details as provided by Massachusetts General Hospital:

Primary Outcome Measures:

- ADHD Clinical Global Impressions Scale - Severity (CGI-S) [Time Frame: 6 months]
  The Clinical Global Impression - Severity scale (CGI-S) is a 7-point scale that requires the clinician to rate the severity of the patient's illness at the time of assessment.

- ADHD Clinical Global Impressions Scale - Improvement (CGI-I) [Time Frame: 6 months]
  The Clinical Global Impression - Improvement scale (CGI-I) is a 7-point scale that requires the clinician to assess how the patient's illness has improved or worsened relative to a baseline state at the beginning of the intervention.

Secondary Outcome Measures:

- Connectomic Variation Prediction of Medicine Response [Time Frame: 6 months]
  Examine whether variation in baseline ADHD severity scores and functional connectivity and structural connectivity predict whether an individual ADHD patient will respond better to one of the other stimulant family treatment, both, or neither. An MRI will be completed prior to starting medication.

Estimated Enrollment: 60

Anticipated Study Start Date: July 1, 2017

Estimated Study Completion Date: December 1, 2019

Estimated Primary Completion Date: July 1, 2019 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
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<tbody>
<tr>
<td>Experimental: Methylphenidate LA (Ritalin)</td>
<td>Drug: Methylphenidate LA (Ritalin)</td>
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<tr>
<td>Adult subjects (ages 18-55) will be randomized to receive either Methylphenidate LA or Mixed Amphetamine Salts (XR). This dose of the</td>
<td>Subjects will be prescribed a titrated dose of Methylphenidate LA for 6</td>
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</table>
stimulant will be titrated with the goal of achieving optimal response and
good tolerability.

Experimental: Mixed Amphetamine Salts XR (Adderall)
Adult subjects (ages 18-55) will be randomized to receive either
Methylphenidate LA or Mixed Amphetamine Salts (XR). This dose of the
stimulant will be titrated with the goal of achieving optimal response and
good tolerability.

Other Name: Ritalin

Drug: Mixed Amphetamine Salts XR (Adderall)
Subjects will be prescribed a titrated
dose of Mixed Amphetamine Salts XR for 6 months.
Other Name: Adderall

Eligibility

Ages Eligible for Study: 18 Years to 55 Years (Adult)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
- Male and female adults ages 18-55
- A diagnosis of DSM-V ADHD based on clinical assessment supported by the ADHD module of a structured
diagnostic interview
- Proficiency in English
- Right-handed

Exclusion Criteria:
- Any contraindication for the use of a stimulant medication
- Investigator and his/her immediate family (spouse, parent, child, grandparent, or grandchild)
- Any contraindications for MRI examination (metallic implants, such as pacemakers, surgical aneurysm clips, or
known metal fragments in the body)
- Women who are currently pregnant or breastfeeding, as confirmed by a urine pregnancy test
- Clinically significant abnormal baseline laboratory values, including systolic and diastolic blood pressure parameters
above 140 and 90, respectively and resting heart rate outside 60-100 bpm

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: NCT03153488

Contacts

Contact: Alexa P Pulli, BS 617-726-4651 apulli@partners.org

Locations
United States, Massachusetts

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Principal Investigator: Joseph Biederman, MD

Massachusetts Institute of Technology

Investigators
Principal Investigator: Joseph Biederman, MD  Massachusetts General Hospital

More Information

Responsible Party: Joseph Biederman, MD, Massachusetts General Hospital
ClinicalTrials.gov Identifier: NCT03153488 History of Changes
Other Study ID Numbers: 2017P000547
Study First Received: May 11, 2017
Last Updated: May 11, 2017

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.: Yes

Keywords provided by Massachusetts General Hospital:
ADHD
Methylphenidate
Amphetamine
Attention Deficit Hyperactivity Disorder Treatment

Additional relevant MeSH terms:
Disease Central Nervous System Stimulants
Attention Deficit Disorder with Hyperactivity Physiological Effects of Drugs
Hyperkinesis Dopamine Uptake Inhibitors
Pathologic Processes Neurotransmitter Uptake Inhibitors
Attention Deficit and Disruptive Behavior Disorders Membrane Transport Modulators
Neurodevelopmental Disorders Molecular Mechanisms of Pharmacological Action
Mental Disorders Dopamine Agents
Dyskinesias Neurotransmitter Agents
Neurologic Manifestations Sympathomimetics
Nervous System Diseases Autonomic Agents
Signs and Symptoms Peripheral Nervous System Agents
Methylphenidate Adrenergic Agents
Adderall
Amphetamine

Adrenergic Uptake Inhibitors

ClinicalTrials.gov processed this record on May 15, 2017