Purpose

Extended release guanfacine (Intuniv) is a FDA approved treatment for Attention-Deficit/Hyperactivity Disorder (ADHD). Clinical trials have shown that extended release of guanfacine (G-EX) is effective in reducing ADHD symptoms, although the neurobiological mechanisms by which G-EX produces these effects remain unknown. The aim of this study is to examine the mechanisms by which G-EX reduces symptoms in patients with ADHD. MRI scanning will be used to understand the structure and blood flow of the brain in children with ADHD.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
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<tbody>
<tr>
<td>Attention Deficit Hyperactivity Disorder</td>
<td>Drug: Guanfacine</td>
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</tbody>
</table>

Study Type: Intervventional

Study Design: Endpoint Classification: Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment
Official Title: Imaging Non-Stimulant Treatment of ADHD

Resource links provided by NLM:

MedlinePlus related topics: Attention Deficit Hyperactivity Disorder

Drug Information available for: Guanfacine Guanfacine hydrochloride

U.S. FDA Resources

Further study details as provided by New York State Psychiatric Institute:

Primary Outcome Measures:

- Changes in brain structure and function as determined by fMRI [ Time Frame: 6 weeks ]
  [ Designated as safety issue: No ]

Estimated Enrollment: 25

Study Start Date: September 2014

Estimated Study Completion Date: July 2015

Estimated Primary Completion Date: July 2015 (Final data collection date for primary outcome measure)

<table>
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<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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</table>
| Experimental: Guanfacine | Drug: Guanfacine
          Subjects will be treated with extended release guanfacine. The guanfacine dose will range between 1-4mg total daily dose and will be titrated according to treatment response. |
|                          | Extended release guanfacine dose will range between 1-4mg total daily dose and will be titrated according to treatment response. Other Name: Intuniv |

Detailed Description:

Fifteen (15) children with ADHD and ten (10) age- and sex-matched, healthy controls will be scanned at the beginning of the study. In this first part of the study, MRI findings will be compared between the groups (i.e., children with and without ADHD) to see whether brain functioning of children with ADHD differs from that of healthy children. In the second part of the study, the children with ADHD will be administered Intuniv for 6 weeks. In the first few weekly visits, the study doctor may adjust the medication dose to optimize its effect. At the end of the study, the children with ADHD will have a second MRI scan. The findings of that second MRI scan will be compared to the first MRI scan in order to examine brain changes due to the medication. These second MRI scans will also be compared to the scans of the healthy controls. The investigators seek to examine whether guanfacine-related changes in the brain structure and function help to reduce symptoms of ADHD.

Eligibility
**Criteria**

**Inclusion Criteria:**

**ADHD Participants:**
- The participant satisfies DSM criteria for a primary diagnosis of ADHD, any subtype.

**Healthy Control Participants:**
- The participant must have no active Axis I psychiatric disorder.

**All Participants:**
- Participants must provide assent and a legal guardian must provide consent.
- The participant is male or female and between 6 - 17 years of age
- Girls of childbearing potential must have a negative urine pregnancy test.
- The participant is English speaking

**Exclusion Criteria:**

**ADHD Participants:**
- The potential participant has a comorbid Axis I psychiatric diagnosis or other symptomatic manifestations that, in the opinion of the examining physician, will contraindicate guanfacine treatment or confound safety assessments.
- The potential participant meets DSM criteria for active substance abuse and/or dependence.
- The potential participant is currently taking, or has taken within the past 4 months, a psychotropic medication.
- The potential participant has a documented allergy or intolerance to guanfacine products.
- The potential participant has a diagnosis or a history of cardiovascular disease, or any other serious medical illness.
- The potential participant is pregnant or lactating.
- The potential participant is actively suicidal.
- MRI contraindications (e.g., irremovable metal on the body, pacemaker, braces, etc.).
- Full Scale Intelligence Quotient (IQ) score < 70.

**Healthy Controls:**
- The potential participant meets DSM criteria for active substance abuse and/or dependence.
- The potential participant is currently taking a psychotropic medication.
- The potential participant has a history of a serious medical illness.
- The potential participant is pregnant or lactating.
- MRI contraindications (e.g., irremovable metal on the body, pacemaker, braces, etc.).
- Full Scale Intelligence Quotient (IQ) score < 70.

**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: NCT02259517
Contacts
Contact: Jonathan Posner, MD  646-774-5735  PosnerJ@nyspi.columbia.edu

Locations

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Principal Investigator: Jonathan Posner, MD

Sponsors and Collaborators
New York State Psychiatric Institute
Columbia University

Investigators
Principal Investigator:  Jonathan Posner, MD  NYSPI

More Information

No publications provided

Responsible Party:  New York State Psychiatric Institute
ClinicalTrials.gov Identifier:  NCT02259517  History of Changes
Other Study ID Numbers:  6961
Study First Received:  September 30, 2014
Last Updated:  October 7, 2014
Health Authority:  United States: Food and Drug Administration
United States: Institutional Review Board

Keywords provided by New York State Psychiatric Institute:
ADHD
Intuniv
Non-stimulant
Guanfacine

Additional relevant MeSH terms:
Disease
Attention Deficit Disorder with Hyperactivity
Hyperkinesis
Attention Deficit and Disruptive Behavior Disorders
Mental Disorders Diagnosed in Childhood
Mental Disorders
Nervous System Diseases
Pathologic Processes
Dyskinesias

Antihypertensive Agents
Cardiovascular Agents
Therapeutic Uses
Pharmacologic Actions
Adrenergic alpha-2 Receptor Agonists
Adrenergic alpha-Agonists
Adrenergic Agonists
Adrenergic Agents
Neurotransmitter Agents
Neurologic Manifestations
Signs and Symptoms
Guanfacine

Molecular Mechanisms of Pharmacological Action
Physiological Effects of Drugs

ClinicalTrials.gov processed this record on October 08, 2014