Purpose

This is an open label pilot study to obtain information on the best way to study young adolescents with Attention Deficit Hyperactivity Disorder (ADHD) who may also be at risk of developing substance abuse, in part because of their ADHD. The plan is to recruit older children/young adolescents (age 11-15) who have ADHD and also have an older sibling with substance abuse. The treatment for ADHD in the 11-15 year old will be Vyvanse, a novel preparation of dextroamphetamine in which the molecule is inactivated and only becomes activated when it is digested. This preparation is felt to be safer from diversion while at the same time providing treatment for the younger siblings in which a bad outcome has already occurred in the family, namely the older sibling's substance abuse. As mentioned, this is an open-label study, a feasibility study to see if we can use this approach to study and treat high risk youth before they develop substance abuse.

Condition

Attention Deficit Hyperactivity Disorder

Intervention

Drug: lisdexamfetamine

Drug: lisdexamfetamine

Phase

Phase 4

Resource links provided by NLM:

MedlinePlus related topics: Attention Deficit Hyperactivity Disorder

Drug Information available for: Lisdexamfetamine Lisdexamfetamine dimesylate

U.S. FDA Resources

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

Primary Outcome Measures:

- Number of Participants With at Least 70% Reduction in ADHD Symptoms as Measured by Change in ADHD Rating Scale From First to Last Visit [ Time Frame: up to 24 weeks ] [ Designated as safety issue: No ]

The outcome is the number of subjects who achieved a clinically meaningful reduction in ADHD symptoms. This is defined as a 70% reduction from baseline as measured by change in the ADHD Rating Scale (ADHD-RS). The ADHD RS quantifies symptoms on a 0-3 scale, 0 meaning never present, 1 sometimes, 2 often present, 3 very often present. For this study, the scale was clinician administered using both parent and adolescent to achieve a consensus score, or a best estimate on the clinician's part when consensus could not be achieved.
Secondary Outcome Measures:

- Number of Participants With Low or no Substance Use During the Study vs the Number With Intermittent Use Judged by (1)Time Line Follow Back (Confidential Clinician Administered Record of Recent Substance Use) (2) Urine Toxicology. [ Time Frame: up to 24 weeks ]
  [ Designated as safety issue: No ]

This outcome measure integrates data from self report supplied in the Time Line Follow Back (a self report summary of all substance and alcohol use over the previous week or month) with evidence from periodic (weekly to monthly) urine toxicologies.

Enrollment: 8
Study Start Date: March 2008
Study Completion Date: March 2010
Primary Completion Date: January 2010 (Final data collection date for primary outcome measure)

Intervention Details:

**Drug:** *lisdexamfetamine*

- Patients will be titrated from 30 mgs to 50 mgs to 70 mgs over four weeks, as tolerated and as needed to control ADHD symptoms
- Other Name: *Lisdexamfetamine* is marketed as *Vyvanse*

**Drug:** *Lisdexamfetamine*

- Capsules 30-70 mgs per day titrated by efficacy and tolerability for up to six months
- Other Name: *Vyvanse*

**Detailed Description:**

The study is a six month open-label treatment with Vyvanse, a novel preparation of the Attention Deficit Hyperactivity Disorder (ADHD) medication dextroamphetamine in which the drug is inactivated and only becomes reactivated when digested. Vyvanse is thought to be safer in youth at risk for substance use disorder because it is harder to abuse and divert. It is FDA approved to treat ADHD in children age 6 through 12. Although there are no negative studies in adolescents 13-15, efficacy has not been established in the latter age group.

In this study 30 adolescents (ages 11-15) will be identified who have Attention Deficit Disorder and are at risk for alcohol and substance use problems. We propose to treat their Attention Deficit Hyperactivity Disorder with Vyvanse in the hope that it may prevent ADHD from promoting the development of alcohol and substance abuse problems. Our main goal is to see if we can identify children who are at risk because they have an older sibling who already has a substance abuse problem and Attention Deficit Hyperactivity Disorder. This is dubbed "the younger sibling design." Families will be recruited via contacts in adolescent substance abuse treatment centers (e.g. Phoenix House, Odyssey House). Participating substance abuse treatment centers will inform families of our study. We will conduct two phone screens followed by an in person evaluation to determine eligibility. Relevant information includes family history with special emphasis on the growth and development of both children, as well as the results of a comprehensive clinical evaluation of the younger child. Subjects will therefore be the younger siblings of substance abusers in which both sibs have ADHD but only the older sib uses drugs or alcohol regularly. All subjects will receive active medication and all will be assessed weekly for the first three months of the study and monthly for three months thereafter. The assessments will focus on ADHD symptoms, substance use, and overall adolescent problem behaviors.

### Eligibility

**Ages Eligible for Study:** 11 Years to 15 Years

**Genders Eligible for Study:** Both

**Accepts Healthy Volunteers:** No

**Criteria**

**Inclusion Criteria:**

- Meets DSM-IV-TR criteria for ADHD
- Has a Gender-Matched older sibling with ADHD and substance dependence
- Medically healthy
- Parents give informed consent
- Child gives assent

**Exclusion Criteria:**

- Significant use of alcohol or marijuana (more than ten episodes) in the past 30 days or any use of cocaine or opiates in the past 30 days; significant nicotine use is not an exclusion
- History of cardiac abnormality, past cardiac problems or family history of the same, history of fainting, open-heart surgery, and arrhythmia
- History of paranoia on stimulant medication
- Seizure or other neurological disturbance
- Pregnancy
- Moderate to severe mental deficiency as determined by IQ <60 or placement in special education for mental deficiency
- Physical exam or laboratory results with significant abnormalities
• Active suicidal or homicidal ideation or history of suicide attempts
• Unequivocal manic or hypomanic episode
• Sexually active females who are unwilling to use effective methods of contraception
• Psychosis or psychosis in a first degree relative
• Current Major Depression
• Individuals who have previously seen a cardiologist until reevaluated by a cardiologist
• Individuals for whom the current cardiac evaluation is not definitive until seen by a cardiologist and given an echocardiogram
• Individuals with Tic disorder
• Significant co-morbid anxiety disorders (i.e., OCD, Panic, PTSD)
• ADHD in remission on another psychostimulant or not in remission but in the context of inadequate dosing of a currently prescribed and administered other psychostimulant

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: NCT00573534

Sponsors and Collaborators

New York State Psychiatric Institute

Investigators

Principal Investigator:  Stephen J Donovan, MD  Columbia University / New York State Psychiatric Institute

More Information

No publications provided

Responsible Party:  Stephen Donovan, Stephen J. Donovan MD, Columbia University, New York State Psychiatric Institute

ClinicalTrials.gov Identifier:  NCT00573534  History of Changes

Other Study ID Numbers:  5522, Shire ISP

Study First Received:  December 12, 2007
Results First Received:  August 15, 2011
Last Updated:  December 9, 2012
Health Authority:  United States: Institutional Review Board

Keywords provided by New York State Psychiatric Institute:

Attention Deficit Hyperactivity Disorder  Prevention
ADHD  Substance use
ADD  Adolescent

Additional relevant MeSH terms:

Attention Deficit Disorder with Hyperactivity  Central Nervous System Stimulants
Hyperkinesis  Physiological Effects of Drugs
Attention Deficit and Disruptive Behavior Disorders  Pharmacologic Actions
Mental Disorders Diagnosed in Childhood  Central Nervous System Agents
Mental Disorders  Therapeutic Uses
Dyskinesias  Dopamine Uptake Inhibitors
Neurologic Manifestations  Dopamine Agents
Nervous System Diseases  Neurotransmitter Agents
Signs and Symptoms  Molecular Mechanisms of Pharmacological Action
Dextroamphetamine  Neurotransmitter Uptake Inhibitors

ClinicalTrials.gov processed this record on October 19, 2014