Mazindol Controlled Release in Adults With Attention Deficit Hyperactivity Disorder (ADHD)

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

Verified June 2016 by NLS Pharma Inc.

Sponsor:
NLS Pharma Inc.

Information provided by (Responsible Party):
NLS Pharma Inc.

ClinicalTrials.gov Identifier:
NCT02808104

First received: June 15, 2016
Last updated: June 16, 2016
Last verified: June 2016
History of Changes

- Full Text View
- Tabular View
- No Study Results Posted
- Disclaimer
- How to Read a Study Record

Purpose
The purpose of this study is to determine whether a controlled release formulation of mazindol is more effective than a placebo in the treatment of Attention Hyperactivity Disorder (ADHD) in adults.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attention Deficit Disorder With Hyperactivity</td>
<td>Drug: mazindol Drug: Placebo</td>
<td>Phase 2</td>
</tr>
</tbody>
</table>

Study Type: Interventional

Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A Double-Blind Placebo-Controlled Phase II Study to Determine the Efficacy, Safety, Tolerability and Pharmacokinetics of a Controlled Release (CR) Formulation of Mazindol in Adults With DSM-5 Attention Deficit Hyperactivity Disorder (ADHD)

Resource links provided by NLM:
Further study details as provided by NLS Pharma Inc.:

Primary Outcome Measures:
- ADHD Rating Scale [ Time Frame: weekly rating up to six weeks ] [ Designated as safety issue: No ]

Secondary Outcome Measures:
- Clinical Global Improvement Scale [ Time Frame: weekly rating up to six weeks ] [ Designated as safety issue: No ]

Estimated Enrollment: 84
Study Start Date: July 2016
Estimated Primary Completion Date: December 2016 (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>Experimental: Mazindol Controlled Release</td>
<td>Drug: mazindol</td>
</tr>
<tr>
<td>Mazindol controlled release taken once daily. Dosage starting at 1 mg increasing or decreasing in increments of 1 mg depending on efficacy and tolerability. Maximum dose during the study is 3 mg taken once daily.</td>
<td></td>
</tr>
<tr>
<td>Placebo Comparator: Placebo</td>
<td>Drug: Placebo</td>
</tr>
<tr>
<td>Matching placebo</td>
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</tr>
</tbody>
</table>

**Detailed Description:**
This study is an outpatient, randomized, double-blind, placebo-controlled trial in which adult subjects with ADHD will be randomized to either oral mazindol controlled release or placebo once daily. Subjects will be treated with study medication or placebo for 6 weeks with visits occurring weekly to measure efficacy and any adverse events with adjustment of medication dosing as necessary.

**Eligibility**
Ages Eligible for Study: 18 Years to 65 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

**Criteria**
Inclusion Criteria:
- Subject has a primary diagnosis of ADHD established by a comprehensive psychiatric evaluation based on DSM-5 criteria.
- Subject is functioning at an appropriate level intellectually as judged by the investigator.
Subject has a minimum baseline score of 28 at screen and at baseline using the ADHD-RS-DSM5.

Subject has a minimum score of 4 (moderate) on the CGI-S at screening.

Women of child-bearing potential must be non-pregnant, non-lactating, and agree to be on an acceptable method of contraception. Acceptable methods of contraception include intrauterine devices (IUDs), hormonal contraceptives (oral, depot, patch or injectable), and double barrier methods such as condoms or diaphragms with spermicidal gel or foam.

In good general physical health as determined by medical history, a baseline physical examination, vital signs, clinical laboratory tests and electrocardiogram (ECG) measurement.

Subject is fluent in written and spoken English and is willing and able to sign written informed consent prior to receipt of any study medication or beginning study procedures.

Subject is willing and able to follow instructions, comply with the protocol requirements and make all required study visits.

Exclusion Criteria:

Any primary DSM-5 Axis I disorder other than ADHD or any comorbid DSM-5 disorder that currently requires treatment.

Lifetime history of any DSM-5 bipolar disorder

Treatment with medications for any psychiatric or neurologic condition (e.g., amphetamines, MPH products, antidepressants, antipsychotics, mood stabilizers, anti-epileptics) or pressor agents concurrently or within 14 days of randomization.

Concurrent medical illness that would interfere with the conduct of the study in the opinion of the investigator.

History of significant cardiovascular disease, structural cardiac abnormality, cardiomyopathy, heart failure, serious heart rhythm abnormalities, coronary heart disease, transient ischemic attack or stroke, or other serious cardiac problems.

Family history of sudden cardiac death.

Clinically significant ECG abnormality or a QTc (Bazett correction) interval >450 msec.

Resting sitting systolic blood pressure > 150 mm Hg or diastolic blood pressure > 90 mm Hg.

BMI <18 or >40 kg/m2.

Other medications that have CNS effects on cognition or attention (e.g., sedating antihistamines or decongestants).

Positive drug screen (UDS) at screening (with the exception of current ADHD medication).

Concomitant use of sensitive CYP4A/5 or CYP2D6 substrates with narrow therapeutic indices.

Pregnant or lactating.

Ongoing psychotherapeutic treatment for the treatment of ADHD begun less than three months before entry into this study.

Recent or current DSM-5 Substance Use Disorder of moderate or greater severity (i.e., > 4 SUD symptoms), excluding nicotine.

Suicidal ideation within past 3 months, suicidal behavior within the past year, or a C-SSRS score of 3, 4 or 5 on ideation item.

Evidence of any out-of-range laboratory value at screening that has not been reviewed, approved and documented as not clinically significant by the Study Investigator.
• A history of significant drug allergy or systemic allergic disease (e.g., urticaria, atopic dermatitis), or any known/suspected hypersensitivity to any form of mazindol.

• Any other condition or clinically significant abnormal findings on the physical examination, medical history, or clinical laboratory results during screening that, in the opinion of the Study Investigator, would make the subject unsuitable for the study or put them at additional risk.

• Treatment with an investigational drug within 30 days preceding the first dose of study medication.

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.

No Contacts or Locations Provided

More Information

Responsible Party: NLS Pharma Inc.
ClinicalTrials.gov Identifier: NCT02808104 History of Changes
Other Study ID Numbers: NLS-1001
Study First Received: June 15, 2016
Last Updated: June 16, 2016
Health Authority: United States: Food and Drug Administration

Additional relevant MeSH terms:
Attention Deficit Disorder with Hyperactivity Adrenergic Agents
Hyperkinesia Adrenergic Uptake Inhibitors
Attention Deficit and Disruptive Behavior Disorders Central Nervous System Stimulants
Dyskinesias Dopamine Agents
Mental Disorders Dopamine Uptake Inhibitors
Nervous System Diseases Membrane Transport Modulators
Neurodevelopmental Disorders Molecular Mechanisms of Pharmacological Action
Neurologic Manifestations Neurotransmitter Agents
Signs and Symptoms Neurotransmitter Uptake Inhibitors
Mazindol Physiological Effects of Drugs

ClinicalTrials.gov processed this record on June 20, 2016