A Study of PDC-1421 Treatment in Adult Patients With Attention-Deficit Hyperactivity Disorder (ADHD)

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

Verified March 2016 by BioLite, Inc.

Sponsor:
BioLite, Inc.

Information provided by (Responsible Party):
BioLite, Inc.

ClinicalTrials.gov Identifier:
NCT02699086

First received: March 1, 2016
Last updated: March 3, 2016
Last verified: March 2016

Purpose

The purpose of this study is to evaluate the safety and efficacy in adult patients with Attention-Deficit Hyperactivity Disorder (ADHD).

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
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</thead>
<tbody>
<tr>
<td>Attention-Deficit Hyperactivity Disorder (ADHD)</td>
<td>Drug: PDC-1421 Capsule</td>
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<tr>
<td></td>
<td>Drug: placebo</td>
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</tbody>
</table>

Study Type: Interventional

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

Resource links provided by NLM:

MedlinePlus related topics: Attention Deficit Hyperactivity Disorder

U.S. FDA Resources
Further study details as provided by BioLite, Inc.:

Primary Outcome Measures:

- ADHD Rating Scale-IV (ADHD-RS-IV) [ Time Frame: 8 weeks ] [ Designated as safety issue: No ]

  The primary endpoint is the change of ADHD Rating Scale-IV (ADHD-RS-IV) total score from baseline to Week 8 compared to placebo.

Secondary Outcome Measures:

- Conners' Adult Attention-Deficit/Hyperactivity Disorder Rating Scale-Self Report: Short Version (CAARS-S:S) [ Time Frame: 8 weeks ] [ Designated as safety issue: No ]

  Change from baseline in the Conners' Adult Attention-Deficit/Hyperactivity Disorder Rating Scale-Self Report: Short Version (CAARS-S:S) 18-Item total ADHD symptom score up to 8 weeks treatment.

- Clinical Global Impression-ADHD- Severity (CGI-ADHD-S) and Clinical Global Impression-ADHD- improvement (CGI-ADHD-I) [ Time Frame: 8 weeks ] [ Designated as safety issue: No ]

  Clinical Global Impression-ADHD- Severity (CGI-ADHD-S) and Clinical Global Impression-ADHD- improvement (CGI-ADHD-I) score of 2 or lower.

- CANTAB [ Time Frame: 8 weeks ] [ Designated as safety issue: No ]

  Difference from baseline to after drug administration in the three CANTAB scores were considered.

Estimated Enrollment: 105

Study Start Date: January 2017

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

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental: 2 PDC-1421 Capsule</td>
<td>Drug: PDC-1421 Capsule</td>
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<tr>
<td>2 PDC-1421 Capsule TID, p.o. after meal for 56 days</td>
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</tr>
<tr>
<td>Experimental: 1 PDC-1421 Capsule plus 1 placebo</td>
<td>Drug: PDC-1421 Capsule Drug: placebo</td>
</tr>
<tr>
<td>1 PDC-1421 Capsule plus 1 placebo TID, p.o. after meal for 56 days</td>
<td></td>
</tr>
<tr>
<td>Placebo Comparator: 2 placebo</td>
<td>Drug: placebo</td>
</tr>
<tr>
<td>2 placebo TID, p.o. after meal for 56 days</td>
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</tbody>
</table>

Eligibility
Ages Eligible for Study: 18 Years to 65 Years

Genders Eligible for Study: Both

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

1. Aged 18-65 years
2. Female subjects of child-bearing potential must test negative to pregnancy and use appropriate birth control method from the beginning of study to the 15 days later after ending of study
3. Subjects must be able to understand and willing to sign informed consent
4. are able to discontinue the use of any psychotropic medications for the treatment of ADHD symptoms at screening
5. meet strict operational criteria for adult ADHD according to the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5)
6. a total score of 20 or higher on the 18-item total ADHD symptoms score of Conners' Adult Attention-Deficit/Hyperactivity Disorder Rating Scale-Self Report:

Conners' Adult Attention-Deficit/Hyperactivity Disorder Rating Scale-Self Report:

Short Version (CAARS-S:S) at screening

7. have a moderate or severe symptom of ADHD with score of 4 or higher in Clinical Global Impression-ADHD-Severity (CGI-ADHD-S) at screening

Exclusion Criteria:

1. have any clinically significant concurrent medical condition (endocrine, renal, respiratory, cardiovascular, hematological, immunological, cerebrovascular, neurological, anorexia, obesity or malignancy) that has become unstable and may interfere with the interpretation of safety and efficacy evaluations
2. have any clinically significant abnormal laboratory, vital sign, physical examination, or electrocardiogram (ECG) findings at screening that, in the opinion of the investigator, may interfere with the interpretation of safety or efficacy evaluations
3. have known serological evidence of human immunodeficiency virus (HIV) antibody
4. are pregnant as confirmed by a positive pregnancy test at screening
5. have QTc values >450 msec at screening using Fridericia’s QTc formula
6. have current of bipolar and psychotic disorders
7. have a current major depression disorder, obsessive-compulsive disorder, post-traumatic stress disorder, generalized anxiety disorder, panic disorder and eating disorder (also if treated but not currently symptomatic)
8. have any history of a significant suicide attempt, or possess a current risk of attempting suicide, in the investigator's opinion, based on clinical interview and responses provided on the Beck Scale for Suicidal Ideation (BSS)
9. have a history of jailing or imprisonment in the past 6 months due to worsening of symptoms of ADHD

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: NCT02699086

Contacts
Contact: Hsien-Ming Wu, Master  886-3-657-9631 ext 13  sonnywu@bioliteinc.com
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Sponsors and Collaborators
BioLite, Inc.

More Information

No publications provided

Responsible Party: BioLite, Inc.
ClinicalTrials.gov Identifier: NCT02699086  History of Changes
Other Study ID Numbers: Phase II BLI-1008-001
Study First Received: March 1, 2016
Last Updated: March 3, 2016
Health Authority: United States: Food and Drug Administration

Additional relevant MeSH terms:
Attention Deficit Disorder with Hyperactivity  Mental Disorders Diagnosed in Childhood
Hyperkinesis  Nervous System Diseases
Attention Deficit and Disruptive Behavior Disorders  Neurologic Manifestations
Dyskinesias  Signs and Symptoms
Mental Disorders

ClinicalTrials.gov processed this record on March 03, 2016