CX717 in the Treatment of Adult ADHD

This study has been completed.

Sponsor:
RespireRx

ClinicalTrials.gov Identifier:
NCT03375021

First Posted: December 15, 2017
Last Update Posted: December 15, 2017

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

Information provided by (Responsible Party):
RespireRx

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

Purpose
A Randomized, Double-Blind, Two-Period Crossover Study to Assess the Efficacy And Safety of the Ampakine® Compound, CX717, versus Placebo in Adults with Attention-Deficit Hyperactivity Disorder

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attention Deficit Hyperactivity Disorder</td>
<td>Drug: CX717 200 mg Drug: CX717 800 mg Drug: Placebo</td>
<td>Phase 2</td>
</tr>
</tbody>
</table>

Study Type: Interventional

Study Design:
Allocation: Randomized
Intervention Model: Crossover Assignment
Intervention Model Description:
- A Randomized, Double-Blind, Two-Period Crossover Study

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Masking Description:
- 200 mg of drug product or placebo in matching size 0 capsules

Primary Purpose: Treatment

Official Title: A Randomized, Double-Blind, Tw0-Period Crossover Study to Assess the Efficacy and Safety of the Ampakine® Compound, CX717, Versus Placebo in Adults With Attention-Deficit Hyperactive Disorder

Resource links provided by NLM:
MedlinePlus related topics: Attention Deficit Hyperactivity Disorder
Further study details as provided by RespireRx:

Primary Outcome Measures:
- ADHD-RS [Time Frame: 3 Weeks]
  Attention-Deficit Hyperactivity Disorder Rating Scale (ADHD-RS) with Prompts. The ADHD-RS is an 18-item scale that assesses the severity of ADHD symptoms based on the symptom list in the DSM-IV. It is administered by a qualified healthcare professional. Each item is rated 0-3 (0=not present and 3=severe). Thus the scale has a range from 0 to 54.

Secondary Outcome Measures:
- ADHD-RS subscales [Time Frame: 3 Weeks]
  Attention Deficit Hyperactivity Disorder Rating Subscales: hyperactivity consisting of items 1-4, 8-10, 17-18, and inattentiveness consisting of items 5-7 and 11-16.
- CGI-I [Time Frame: 3 Weeks]
  Clinical Global Impression of Improvement
- HAM-A [Time Frame: 3 Weeks]
  Hamilton Rating Scale of Anxiety
- HAM-D [Time Frame: 3 Weeks]
  Hamilton Rating Scale of Depression
- PSQI [Time Frame: 3 Weeks]
  Pittsburgh Sleep Quality Index
- ESS [Time Frame: 3 Weeks]
  Eppworth Sleepiness Scale
- ADHD-SRS [Time Frame: 3 Weeks]
  Attention Deficit Hyperactivity Disorder Self Rating Scale
- SCWT [Time Frame: 3 Weeks]
  Stroop Color and Word Test
- CTMT [Time Frame: 3 Weeks]
  Comprehensive Trail Making Test
- CPT [Time Frame: 3 Weeks]
  Continuous Performance Task
- FBDS [Time Frame: 3 Weeks]
  Forward and Backward Digit Span
Enrollment: 68
Actual Study Start Date: July 19, 2005
Study Completion Date: January 10, 2006
Primary Completion Date: January 10, 2006 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
</table>
| Experimental: Sequence 1 PL  
Eligible subjects were randomized to Sequence 1 PL in which they received placebo (P) followed by crossover to CX717 200 mg low dose (L) of active treatment | Drug: CX717 200 mg  
CX717 200 mg capsules BID  
Other Name: Low Dose  
Drug: Placebo  
Placebo 200 mg or 800 mg capsules BID |
| Experimental: Sequence 2 PH  
Eligible subjects were randomized to Sequence 2 PH in which they received placebo (P) followed by crossover to CX717 800 mg High dose (H) of active treatment | Drug: CX717 800 mg  
CX717 4 X 200 mg capsules BID  
Other Name: High Dose  
Drug: Placebo  
Placebo 200 mg or 800 mg capsules BID |
| Experimental: Sequence 3 LP  
Eligible subjects were randomized to Sequence 3 LP in which they received CX717 200 mg Low dose (L) of active treatment followed by crossover to placebo (P) | Drug: CX717 200 mg  
CX717 200 mg capsules BID  
Other Name: Low Dose  
Drug: Placebo  
Placebo 200 mg or 800 mg capsules BID |
| Experimental: Sequence 4 HP  
Eligible subjects were randomized to Sequence 2 PH in which they received CX717 800 mg High dose (H) of active treatment followed by crossover to placebo (P) | Drug: CX717 800 mg  
CX717 4 X 200 mg capsules BID  
Other Name: High Dose  
Drug: Placebo  
Placebo 200 mg or 800 mg capsules BID |

**Detailed Description:**
This study examined the clinical efficacy, tolerability and safety of CX717 in the treatment of adults with ADHD. The study was a double-blind, 2-period crossover study that compared 2 different doses of CX717 with placebo. Subjects were randomized to 1 of 4 different treatment sequences: placebo - low dose; low dose - placebo; placebo - high dose; or high dose - placebo. Each treatment period was 3 weeks with a 2-week washout between treatment periods. The doses chosen were 200 mg b.i.d. and 800 mg b.i.d.

**Eligibility**

**Information from the National Library of Medicine**

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, Learn About Clinical Studies.
Ages Eligible for Study: 18 Years to 50 Years (Adult)
Sexes Eligible for Study: Male
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
1. Subject had ADHD as established by the Adult ADHD Clinical Diagnostic Scale (ACDS) Version 1.2
2. Patients must have at least moderately severe ADHD symptoms:
   - Subject had an ADHD-RS score of \( \geq 22 \)
   - Subject had a CGI-S score of \( \geq 4 \)
3. Subject was male
4. Subject was 18 - 50 years old, inclusive
5. Subject could read well enough to understand the informed consent form and other patient materials.

Exclusion Criteria:
1. Subject had a DSM-IV diagnosis of ADHD not otherwise specified
2. Subject had a current or lifetime history of bipolar disorder or any psychotic disorder as established by the Structured Clinical Interview for DSM-IV (SCID) (12)
3. Subject had a current history of major depression, substance abuse or dependence, generalized anxiety disorder, obsessive compulsive disorder, panic disorder, or posttraumatic stress disorder as established by SCID
4. Subject had a history of epilepsy, seizures, syncope, unexplained blackout spell(s), head trauma with loss of consciousness, or febrile seizures
5. Subject had a currently active medical condition (other than ADHD) that in the opinion of the Investigator could interfere with the ability of subject to participate in the study
6. Subject had a history of development delay in milestones
7. By history, the subject had an IQ less than 80
8. In the opinion of the Investigator, the subject had not derived significant therapeutic benefit from 2 or more appropriately dosed ADHD therapies
9. Subject was currently taking medication specifically for treatment of ADHD symptoms (e.g., stimulants, atomoxetine, tricyclic antidepressants, or bupropion).
   NOTE: subjects were off of stimulants for 2 weeks and off non-stimulant ADHD therapies for 4 weeks prior to the Period 1 Baseline Visit. Subject did not have evidence of a discontinuation or withdrawal reaction.
10. Subject was currently taking an anti-depressant prescription medication (e.g., paroxetine, sertraline, venlafaxine, etc.) or St. John's Wort
11. Subject was currently taking an anti-convulsant medication (e.g., phenytoin, carbamazepine, lamotrigine, valproic acid, etc.) or anti-psychotic medication
12. Subject had a clinically relevant abnormality on Screening evaluation including physical examination, vital signs, ECG, or laboratory tests
13. Subject was currently taking on a chronic basis any medication known to be primarily metabolized by a route other than the cytochrome P450 system
14. Subject was unwilling to refrain from taking medications that may have interfered with the assessment of cognitive function. Examples included benzodiazepines, sedating anti-histamines, zolpidem, and zaleplon. Herbal preparations with effects on the central nervous system (e.g., St. John's Wort, melatonin) were prohibited. These medications and herbal preparations were also prohibited throughout the study.
15. Subject was unwilling to refrain from taking more than 1 unit of alcohol within 24 hours of the clinic visits
16. Subject had a Body Mass Index (BMI) of less than 18 or greater than 35. No waivers were allowed.
17. Subject reported passive or active suicidal ideation or intent
18. Subject was concurrently participating in another clinical research study or investigational drug trial or had participated within the past 1 month
19. Subject was at high risk of non-compliance in the Investigator's opinion

Contacts and Locations
Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): **NCT03375021**

Sponsors and Collaborators
RespireRx

Investigators

Principal Investigator: Len Adler, MD  NYU School of Medicine

More Information

Responsible Party: RespireRx
ClinicalTrials.gov Identifier: NCT03375021  History of Changes
Other Study ID Numbers: CX717-05-ADHD
First Submitted: December 7, 2017
First Posted: December 15, 2017
Last Update Posted: December 15, 2017
Last Verified: December 2017

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

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.: No

Keywords provided by RespireRx:
ADHD, ampakine, Phase II clinical trial

Additional relevant MeSH terms:
Attention Deficit Disorder with Hyperactivity
Attention Deficit and Disruptive Behavior Disorders
Neurodevelopmental Disorders
Mental Disorders