A 6-week Study to Evaluate the Safety and Efficacy of Methylphenidate HCl ERCT in 4-5 Year Old Children With ADHD

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. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT03556390

Recruitment Status: Not yet recruiting
First Posted: May 24, 2018
Last Update Posted: May 24, 2018

See Contacts and Locations

Sponsor:
Pfizer

Information provided by (Responsible Party):
Pfizer

---

**Study Details**

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

**Study Description**

**Brief Summary:**
This 6-week study is to determine if the study drug, Methylphenidate Hydrochloride (HCl) Extended-Release Chewable Tablets (ERCT), is safe, tolerable and effective when compared to a sugar pill or placebo in children 4 to 5 years of age with ADHD.

<table>
<thead>
<tr>
<th>Condition or disease</th>
<th>Intervention/treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attention Deficit Hyperactivity Disorder</td>
<td>Drug: Methylphenidate Hydrochloride (HCl) Extended Release Chewable Tablets (ERCT) Placebo</td>
</tr>
</tbody>
</table>

**Detailed Description:**
Phase 4 Double-blind, Randomized, Parallel Group, Placebo-controlled Study of the Efficacy And Safety of Methylphenidate Hydrochloride (HCl) Extended Release Chewable Tablets (ERCT) In 4-5 Year Old Children With Attention Deficit Hyperactivity Disorder (ADHD)

**Study Design**

Go to ▼

- **Study Type:** Interventional (Clinical Trial)
- **Estimated Enrollment:** 80 participants
- **Allocation:** Randomized
- **Intervention Model:** Parallel Assignment
Intervention Model Description: Double-blind, placebo-controlled, parallel group study.

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Masking Description: Double-blind

Primary Purpose: Treatment

Official Title: A Phase 4, Double-blind, Randomized, Parallel Group, Placebo-controlled Study Of The Efficacy And Safety Of Methylphenidate Hydrochloride (Hcl) Extended Release Chewable Tablet (Erct) In 4-5 Year Old Children With Attention Deficit Hyperactivity Disorder (Adhd)

Estimated Study Start Date: June 2018

Estimated Primary Completion Date: January 2021

Estimated Study Completion Date: January 2021

Resource links provided by the National Library of Medicine
MedlinePlus related topics: Attention Deficit Hyperactivity Disorder

Drug Information available for: Methylphenidate Methylphenidate hydrochloride

U.S. FDA Resources

Arms and Interventions
Go to ▼

<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention/treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo Comparator: Placebo one chewable tablet once daily in morning.</td>
<td>Drug: Placebo Placebo</td>
</tr>
<tr>
<td>Experimental: Methylphenidate Hydrochloride Extended Release Chewable Tablet one chewable tablet once daily in morning.</td>
<td>Drug: Methylphenidate Hydrochloride (Hcl) Extended Release Chewable Tablet (ERCT) Methylphenidate Hydrochloride (Hcl) Extended Release Chewable Tablet (ERCT)</td>
</tr>
</tbody>
</table>

Outcome Measures
Go to ▼

Primary Outcome Measures:
1. Attention Deficit Hyperactivity Rating Scale - IV (ADHD RS-IV) Preschool—Home Version [ Time Frame: 6 Weeks ]

   Change from Baseline to end of double-blind treatment in the total score of the Attention Deficit Hyperactivity Rating Scale - IV (ADHD RS-IV) Preschool—Home Version

Secondary Outcome Measures:
1. Safety-incidence of treatment emergent adverse events [ Time Frame: 6 Weeks ]

   incidence of treatment emergent adverse events
2. Change from Baseline in Clinical Global Impression - Severity (CGI-S) score [Time Frame: Baseline, Weeks 1 through 6]

The CGI-S is a one-item scale for the clinician to assess their impression of the severity of a subject's current state of illness relative to clinician's past experience with patients who have the same diagnosis. A subject's severity of mental illness is assessed considering a clinician’s total clinical experience using a scale from 1 to 7 defined as: 1=normal, not at all ill; 2=borderline mentally ill; 3=mildly ill; 4=moderately ill; 5=markedly ill; 6=severely ill; or 7=extremely ill.

3. Change from Baseline in Clinical Global Impression of Improvement (CGI-I) Scale Score [Time Frame: Weeks 1 through 6]

The CGI-I is a one-item scale to compare the subject's current condition to the condition at the Baseline (Day-1) visit using a scale from 1 to 7 defined as: 1=very much improved since the initiation of treatment; 2=much improved; 3=minimally improved; 4=no change from baseline (the initiation of treatment); 5=minimally worse; 6= much worse; 7=very much worse since the initiation of treatment.

4. ADHD RS-IV Preschool—Home Version Total score [Time Frame: Weeks 1 through 5]

The ADHD RS-IV Preschool Version is an 18-item scale corresponding to the 18 items in the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, Text Revision criteria that is divided into 2 subscales: hyperactivity/impulsivity and inattentiveness. Each item is scored on a 4-point scale ranging from 0 = never/rarely to 3 = very often.

5. ADHD RS-IV Preschool—Home Version hyperactivity and inattention subscales scores [Time Frame: Weeks 1 through 6]

The ADHD RS-IV Preschool Version is an 18-item scale corresponding to the 18 items in the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, Text Revision criteria that is divided into 2 subscales: hyperactivity/impulsivity and inattentiveness. Each item is scored on a 4-point scale ranging from 0 = never/rarely to 3 = very often.

6. ADHD RS-IV Preschool—School Version Total score [Time Frame: Weeks 3 and 6]

The ADHD RS-IV Preschool - School Version will be completed by the subject's teacher.

7. ADHD RS-IV Preschool—School Version hyperactivity and inattention subscales scores [Time Frame: Weeks 3 and 6]

The ADHD RS-IV Preschool - School Version will be completed by the subject's teacher.

Eligibility Criteria

Go to ▼
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: 48 Months to 69 Months (Child)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

1. Male or female child 4-5 years of age at screening.
2. Signed and dated informed consent provided by the subject's parent/legal and assent of the child (as applicable).
3. Meets DSM-5 criteria for ADHD based on the K-SADS-PL.
4. ADHD RS-IV Preschool—Home Version score at Screening and Baseline >/= 90th percentile for gender and age in >/=1 of the following: hyperactive-impulsive subscale, inattentive subscale, or total score.
6. Child Global Assessment Scale (CGAS) score </= 55.
7. Participation in a school type program (day care, preschool, kindergarten, transitional kindergarten, or elementary school) for at least >/=2 half days of the week for at least 3 months and that is anticipated to continue during the study.
8. History of an adequate course of non medication treatment for ADHD based on investigator judgment or, where such treatments are not available, the severity of the subject's ADHD symptoms are such that medication treatment is deemed necessary by the investigator

Exclusion Criteria:

1. Treated with atomoxetine within 30 days prior to the Baseline.
2. Received any investigational products or devices within 30 days prior to the Baseline visit.
3. History of stimulant nonresponse, intolerability or hypersensitivity to any dose of methylphenidate or other stimulant. If a known allergy to D&C red #30, he/she should not be enrolled in the study.
4. An intelligence quotient (IQ) <70.
5. History of acute or chronic medical or psychiatric condition or cardiac or laboratory abnormality.
6. Less than 5th percentile for height or weight at Screening.
7. History of recent clinically significant self-harming behaviors.

Contacts and Locations

Go to ▼

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): NCT03536390

Contacts

Contact: Pfizer CT.gov Call Center 1-800-718-1021 ClinicalTrials.gov Inquiries@pfizer.com
Sponsors and Collaborators
Pfizer

Investigators
Study Director: Pfizer CT.gov Call Center Pfizer

More Information
Go to ▼

Additional Information:
To obtain contact information for a study center near you, click here.
To obtain contact information for a study center near you, click here.
To obtain contact information for a study center near you, click here.
To obtain contact information for a study center near you, click here.

Responsible Party: Pfizer

ClinicalTrials.gov Identifier: NCT03536390

History of Changes

Other Study ID Numbers: B7491017

First Posted: May 24, 2018

Last Update Posted: May 24, 2018

Last Verified: May 2018

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: Yes
Plan Description: Information relating to our policy on data sharing and the process for requesting data can be found at the following link: http://www.pfizer.com/research/clinical_trials/trial_data_and_results/data_requests

URL: http://

Studies a U.S. FDA-regulated Drug Product: Yes
Studies a U.S. FDA-regulated Device Product: No

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