6 Month OL Study to Evaluate the Safety, Tolerability and Efficacy of Methylphenidate HCl ERCT in 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: NCT03580005

Recruitment Status : Not yet recruiting
First Posted : July 9, 2018
Last Update Posted : July 9, 2018
See **Contacts and Locations**

**Sponsor:**
Pfizer

**Information provided by (Responsible Party):**
Pfizer

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**Study Details**

**Tabular View**

**No Results Posted**

**Disclaimer**

**How to Read a Study Record**

**Study Description**

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**Brief Summary:**
6-month open label study to evaluate the safety, tolerability and efficacy of methylphenidate HCl ERCT in children with ADHD

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**Condition or disease**

Attention Deficit Hyperactivity Disorder (ADHD)

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**Detailed Description:**
6 month open label study to evaluate the safety, tolerability and efficacy of methylphenidate HCl ERCT in preschool aged children with ADHD who participated in study B7491017 or B7491020.

**Study Design**

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- **Study Type:** Interventional (Clinical Trial)
- **Estimated Enrollment:** 88 participants
- **Intervention Model:** Single Group Assignment
- **Masking:** None (Open Label)
- **Primary Purpose:** Treatment
Official Title: A Phase 4, 6-month Open-label Extension Study To Evaluate The Safety, Tolerability And Efficacy Of Quillichew (Methylphenidate Hydrochloride (Hcl)) Extended Release Chewable Tablets (Erct) In Children With Attention Deficit Hyperactivity Disorder (Adhd) Who Participated In Study B7491017 Or Study B7491020.

Estimated Study Start Date: October 31, 2018
Estimated Primary Completion Date: October 12, 2021
Estimated Study Completion Date: October 12, 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
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<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention/treatment</th>
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</thead>
<tbody>
<tr>
<td>methylphenidate HCl ERCT</td>
<td>Drug: methylphenidate HCl ERCT</td>
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<tr>
<td>methylphenidate HCl ERCT</td>
<td>methylphenidate HCl ERCT</td>
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Outcome Measures
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Primary Outcome Measures:
1. Safety-incidence of treatment emergent adverse events [Time Frame: 6 months]
   incidence of treatment emergent adverse events

Eligibility Criteria
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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: 4 Years to 5 Years (Child)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria
Inclusion Criteria:
1. Male or female child who participated in B7491017 or B7491020.
2. Signed and dated informed consent provided by the subject's parent/legal and assent of the child (as applicable).
3. Willing and able to comply with scheduled visit, treatment plan, laboratory tests and other study procedures.
4. Sitting systolic or diastolic blood pressure (BP) <95th percentile for age, sex, and height.

Exclusion Criteria:

1. Clinically significant AEs or SAEs related to investigational product while participating in study B7491017 or study B7491020 that would preclude treatment with methylphenidate HCl ERCT.
2. Other acute or chronic medical or psychiatric condition that would make the patient inappropriate for entry.
3. Use of prohibited concomitant treatments.
4. Poor compliance with investigational product or study procedures.

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): NCT03580005

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

Additional Information:

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

Responsible Party: Pfizer

ClinicalTrials.gov Identifier: NCT03580005  History of Changes

Other Study ID Numbers: B7491019

First Posted: July 9, 2018  Key Record Dates

Last Update Posted: July 9, 2018

Last Verified: June 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
- Hyperkinesis
- Attention Deficit and Disruptive Behavior Disorders
- Neurodevelopmental Disorders
- Mental Disorders
- Dyskinesias
- Neurologic Manifestations
- Nervous System Diseases
- Signs and Symptoms

- Methylphenidate
- Central Nervous System Stimulants
- Physiological Effects of Drugs
- Dopamine Uptake Inhibitors
- Neurotransmitter Uptake Inhibitors
- Membrane Transport Modulators
- Molecular Mechanisms of Pharmacological Action
- Dopamine Agents
- Neurotransmitter Agents