Safety, Tolerability and PK Study 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: NCT03546400

Recruitment Status: Not yet recruiting
First Posted: June 5, 2018
Last Update Posted: June 5, 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

Go to ▼

Brief Summary:
2-week open-label safety, tolerability and pharmacokinetic study of methylphenidate HCl ERCT in 4-5 year old children with ADHD.

Condition or disease

Attention Deficit Hyperactivity Disorder (ADHD)

Detailed Description:

Phase 4, Open-label, Safety, Tolerance And Pharmacokinetic Study 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: 8 participants

Intervention Model: Single Group Assignment

Masking: None (Open Label)

Primary Purpose: Treatment

Official Title: A Phase 4, Open-label, Safety, Tolerance And Pharmacokinetic Study Of Methylphenidate Hydrochloride (Hcl) Extended Release Chewable Tablet
In 4-5 Year Old Children With Attention Deficit Hyperactivity Disorder (Adhd)

Estimated Study Start Date: June 27, 2018

Estimated Primary Completion Date: September 4, 2020

Estimated Study Completion Date: September 4, 2020

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>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

Go to ▼

Primary Outcome Measures:

1. PK parameter-Tmax [Time Frame: 2 weeks]

   PK profile of methylphenidate following a single oral dose of 30 mg methylphenidate HCl ERCT.

2. PK parameter- Cmax [Time Frame: 2 weeks]

   PK profile of methylphenidate following a single oral dose of 30 mg methylphenidate HCl ERCT.

3. PK parameter- AUClast [Time Frame: 2 weeks]

   PK profile of methylphenidate following a single oral dose of 30 mg methylphenidate HCl ERCT.

4. PK parameter-AUC0-2 [Time Frame: 2 weeks]

   PK profile of methylphenidate following a single oral dose of 30 mg methylphenidate HCl ERCT.

5. PK parameter-AUC2-6 [Time Frame: 2 weeks]

   PK profile of methylphenidate following a single oral dose of 30 mg methylphenidate HCl ERCT.
6. PK parameter-AUC6-24 [Time Frame: 2 weeks]
   PK profile of methylphenidate following a single oral dose of 30 mg methylphenidate HCl ERCT.

7. PK parameter-AUCinf [Time Frame: 2 weeks]
   PK profile of methylphenidate following a single oral dose of 30 mg methylphenidate HCl ERCT.

8. PK parameter- t1/2 [Time Frame: 2 weeks]
   PK profile of methylphenidate following a single oral dose of 30 mg methylphenidate HCl ERCT.

9. PK parameter-CL/F [Time Frame: 2 weeks]
   PK profile of methylphenidate following a single oral dose of 30 mg methylphenidate HCl ERCT.

10. PK parameter-Vz/F [Time Frame: 2 weeks]
    PK profile of methylphenidate following a single oral dose of 30 mg methylphenidate HCl ERCT.

Secondary Outcome Measures:
1. incidence of treatment emergent adverse events (safety and tolerability) [Time Frame: 2 weeks]
   incidence of treatment emergent adverse events (safety and tolerability)

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. 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 subject has 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): NCT03546400

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.

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Responsible Party: Pfizer
ClinicalTrials.gov Identifier: NCT03546400

Other Study ID Numbers: B7491020
First Posted: June 5, 2018
Last Update Posted: June 5, 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_request
   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
Attention Deficit and Disruptive Behavior 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