Dose Response Effects of Quillivant XR in Children With ADHD and Autism: A Pilot Study

This study is currently recruiting participants. (see Contacts and Locations)

Verified September 2014 by Seattle Children's Hospital

Sponsor:
Seattle Children's Hospital

Collaborator:
Pfizer

Information provided by (Responsible Party):
Mark Stein, Seattle Children's Hospital

ClinicalTrials.gov Identifier:
NCT02255565

First received: September 24, 2014
Last updated: September 29, 2014
Last verified: September 2014

Purpose

The purpose of this study is to determine whether Quillivant XR is effective in the treatment of ADHD in children with Autism Spectrum Disorder (ASD).

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADHD</td>
<td>Drug: Very Low <strong>Dose Quillivant XR</strong></td>
<td>Phase 4</td>
</tr>
<tr>
<td>Autism</td>
<td>Drug: Low <strong>Dose Quillivant XR</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Drug: Moderate <strong>Dose Quillivant XR</strong></td>
<td></td>
</tr>
</tbody>
</table>
Study Type: Interventional

Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Single Blind (Outcomes Assessor)
Primary Purpose: Treatment

Official Title: **Quillivant XR in Children With Attention Deficit/Hyperactivity Disorder (ADHD) and Autism Spectrum Disorder (ASD): A Pilot Study**

Resource links provided by NLM:

MedlinePlus related topics: Autism

Drug Information available for: Methylphenidate Methylphenidate hydrochloride

Genetic and Rare Diseases Information Center resources: Children's Interstitial Lung Disease

U.S. FDA Resources

Further study details as provided by Seattle Children's Hospital:

Primary Outcome Measures:

- **ADHD Rating Scale - IV** [Time Frame: Measure changes from baseline once a week for 6 weeks] [Designated as safety issue: No]

  Obtains parent ratings regarding the frequency of each ADHD symptom based on DSM-IV criteria

Secondary Outcome Measures:

- **Clinical Global Impressions-ADHD** - Severity and Improvement scales [Time Frame: Measure changes from baseline once a week for 6 weeks] [Designated as safety issue: No]

  A clinician rated 7-point scale that describes the severity of ADHD symptoms or improvement (or worsening) of ADHD symptoms as compared to baseline.

Estimated Enrollment: 25

Study Start Date: September 2014
Estimated Study Completion Date: December 2016

Estimated Primary Completion Date: October 2016 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental: Very Low Dose Quillivant XR</td>
<td>Drug: Very Low Dose Quillivant XR</td>
</tr>
<tr>
<td>Patients in this treatment arm are given Quillivant XR (a liquid medication) to treat ADHD at a very low dose level for 6 weeks.</td>
<td>Oral suspension dose once a day increasing to a 10mg dose</td>
</tr>
<tr>
<td></td>
<td>Other Name: Methylphenidate HCl</td>
</tr>
<tr>
<td>Experimental: Low Dose Quillivant XR</td>
<td>Drug: Low Dose Quillivant XR</td>
</tr>
<tr>
<td>Patients in this treatment arm are given Quillivant XR (a liquid medication) to treat ADHD at a low dose level for 6 weeks.</td>
<td>Oral suspension dose once a day increasing to a 20mg dose</td>
</tr>
<tr>
<td></td>
<td>Other Name: Methylphenidate HCl</td>
</tr>
<tr>
<td>Experimental: Moderate dose Quillivant XR</td>
<td>Drug: Moderate Dose Quillivant XR</td>
</tr>
<tr>
<td>Patients in this treatment arm are given Quillivant XR (a liquid medication) to treat ADHD at a moderate dose level for 6 weeks.</td>
<td>Oral suspension dose once a day increasing to a 40mg dose</td>
</tr>
<tr>
<td></td>
<td>Other Name: Methylphenidate HCl</td>
</tr>
</tbody>
</table>

**Detailed Description:**

To evaluate the safety and tolerability of low to moderate dose effects of Quillivant XR (liquid methylphenidate) and to observe changes in ADHD symptoms and functional outcomes in children with ASD and ADHD. The investigators propose to investigate the low to moderate dose range of methylphenidate compared with a very low dose with a gradual dose escalation schedule because children with ASD have been found to be more sensitive to the adverse effects of methylphenidate (especially in medium to high doses) than children without ASD.

**Eligibility**

Ages Eligible for Study: 6 Years to 16 Years

Genders Eligible for Study: Both

Accepts Healthy Volunteers: No

**Criteria**

Inclusion Criteria:

- A clinical diagnosis of Autistic disorder or Asperger's disorder by DSM-IV or Autism Spectrum Disorder by DSM-V.
- A DSM-V diagnosis of ADHD based upon the K-SADS-P.
- Clinical Global Impressions - Severity for ADHD (CGI-S-ADHD) rating > 4.
• Findings on physical exam, labs and ECG are judged to be normal for age with pulse and blood pressure within 95% of age and gender mean.

• Informed consent by a parent or legal guardian, and assent for children with developmental age 7 years or older.

• At least one parent fluent in English

Exclusion Criteria:

• History of Seizure disorder (Febrile seizures are non-exclusionary).

• History of Intellectual Disability (IQ < 70)

• Treatment with MAO Inhibitor (or within 14 days following discontinuation of MAO Inhibitor).

• Other psychotropic medication other than stable dose of Selective Serotonin Reuptake Inhibitors, which is permitted

• Known to be hypersensitive to methylphenidate, or other components of Quillivant XR

• Cardiac or other medical contraindications for stimulant trial (e.g., family history of heart attack at age younger than 40 years, personal history of heart disease, history of fainting while exercising, structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmias, coronary artery disease, or other serious cardiac problems. If any doubt, children will be referred to a cardiologist for a cardiac clearance.

• Raynaud's disease

• Pregnancy or Breast-feeding.

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: NCT02255565

Contacts

Contact: Sophie Shonka, BS 206-884-7838 sophia.shonka@seattlechildrens.org

Locations

United States, Washington

Seattle Children's Hospital  Recruiting

Seattle, Washington, United States, 98105

Contact: Libby Bliss, MA  206-884-1488 elizabeth.bliss@seattlechildrens.org

Principal Investigator: Mark A Stein, Ph.D

Sponsors and Collaborators

Seattle Children's Hospital
Pfizer

Investigators

Principal Investigator: Mark Stein, PhD  Seattle Children's

Publications:


Responsible Party: Mark Stein, Director of ADHD/Related Disorders Program, Seattle Children's Hospital

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Other Study ID Numbers: WI185890

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Health Authority: United States: Institutional Review Board

Keywords provided by Seattle Children's Hospital:

Quillivant

Additional relevant MeSH terms:

Autistic Disorder  Pharmacologic Actions
Attention Deficit Disorder with Hyperactivity  Central Nervous System Agents
Child Development Disorders, Pervasive  Therapeutic Uses
Methylphenidate  Dopamine Uptake Inhibitors
Physiological Effects of Drugs  Dopamine Agents
Mental Disorders Diagnosed in Childhood  Neurotransmitter Agents
Mental Disorders  Molecular Mechanisms of Pharmacological Action
Attention Deficit and Disruptive Behavior Disorders  
Central Nervous System Stimulants  
Neurotransmitter Uptake Inhibitors

ClinicalTrials.gov processed this record on October 03, 2014