Extended-release Guanfacine Hydrochloride in Children/Adolescents With Attention-deficit/Hyperactivity (SPD503-315)

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.

ClinicalTrials.gov Identifier: NCT03662763

Recruitment Status : Completed
First Posted : September 7, 2018
Last Update Posted : September 7, 2018

Sponsor:
Maastricht University Medical Center

Collaborator:
Shire

Information provided by (Responsible Party):
Maastricht University Medical Center

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**Study Details**

- **Tabular View**
- **No Results Posted**

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**Condition or disease** | **Intervention/treatment**
---|---
Attention Deficit Disorder | Drug: Extended-release Guanfacine Hydrochloride (SPD503)

**Detailed Description:**
The SPD503-315 clinical program has studied the efficacy, safety, and tolerability of this product in treating symptoms of ADHD in children and adolescents aged 6-17 through short-term, placebo-controlled studies and long-term, open-label studies. This study will more rigorously assess the long-term maintenance of efficacy using a placebo-controlled, randomised-withdrawal design. To date, all of the completed studies conducted as part of the SPD503 program have enrolled subjects from the US. This study is designed to evaluate the long-term maintenance of efficacy of SPD503 for the treatment of ADHD in children aged 6-17 years in Europe, Australia, Canada and the US.

**Study Design**

- **Study Type** : Interventional (Clinical Trial)
- **Actual Enrollment** : 12 participants
- **Allocation** : Randomized
Intervention Model: Parallel Assignment

Masking: Double (Participant, Investigator)

Primary Purpose: Treatment

Official Title: Phase 3, Double Blind, Placebo-controlled, Multicentre, Randomised-withdrawal, Long-term Maintenance of Efficacy & Safety Study of Extended-release Guanfacine Hydrochloride in Children/Adolescents Aged 6-17 With ADHD

Actual Study Start Date: September 2011

Actual Primary Completion Date: August 2013

Actual Study Completion Date: December 2013

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

Drug Information available for: Guanfacine Guanfacine hydrochloride

U.S. FDA Resources

Arms and Interventions

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<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention/treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo Comparator: Placebo</td>
<td>Drug: Placebo oral capsule</td>
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<tr>
<td>Experimental: Extended-release Guanfacine Hydrochloride (SPD503)</td>
<td>Drug: Extended-release Guanfacine Hydrochloride (SPD503) dosing in all subjects will initiate with 1mg/day, and may be increased by 1 mg increments after a minimum of 1 week on the current dose to the maximum doses based on age and weight. Other Names:</td>
</tr>
<tr>
<td></td>
<td>• Extended-release Guanfacine Hydrochloride</td>
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<td></td>
<td>• SPD503</td>
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Outcome Measures

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Primary Outcome Measures:

1. Attention Deficit Hyperactivity Disorder-Rating Scale -IV [Time Frame: 13 weeks]

Secondary Outcome Measures:

1. Clinical Global Impressions-Severity score [Time Frame: 13 weeks]

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:** 6 Years to 17 Years (Child)

**Sexes Eligible for Study:** All

**Accepts Healthy Volunteers:** No

**Criteria**

**Inclusion Criteria:**
- male or female, aged 6-17 years at the time of consent/assent at Screening/Visit 1
- subject meets DSM-IV-TR criteria for primary diagnosis of ADHD
- subject has a minimum ADHD-RS-IV total score of 32 at enrolment/visit 2
- subject has a minimum CGI-S score of 4 at enrolment/Visit 2
- subject is able to swallow intact tablets

**Exclusion Criteria:**
- subject has a current controlled or uncontrolled, co-morbid psychiatric diagnosis.
- subject has a known history or presence of structural cardiac abnormalities
- subject with orthostatic hypotension or a known history of controlled or uncontrolled hypertension
- current use of any prohibited medication or other medications, including herbal supplements that affect blood pressure, or heart rate or that have CNS effects or affect cognitive performance
- subject is significantly overweight based on Centre for Disease Control and Prevention BMI for age, gender specific charts. Significantly overweight is defined as a BMI >95th percentile Children aged 6-12 years with a body weight >25.0 kg, or adolescents aged 13-17 years with a body weight <43 kg or >91 kg at screening/visit 1
- subject is currently considered a suicide risk in the opinion of the investigator
- history of failure to respond to an adequate trial of an alpha2-agonist for the treatment of ADHD.

**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): NCT03662763*

**Locations**

**Netherlands**
Maastricht University Medical Centre
Maastricht, Netherlands

**Sponsors and Collaborators**
Maastricht University Medical Center
Shire

**Investigators**
Principal Investigator: Andries Korebrits, prof. Dr. psychiatrie

**More Information**

Go to Responsible Party: Maastricht University Medical Center
ClinicalTrials.gov Identifier: NCT03662763  History of Changes
Other Study ID Numbers: 101081
First Posted: September 7, 2018  Key Record Dates
Last Update Posted: September 7, 2018
Last Verified: September 2018

Additional relevant MeSH terms:
Attention Deficit Disorder with Hyperactivity  Adrenergic alpha-Agonists
Attention Deficit and Disruptive Behavior Disorders  Adrenergic Agonists
Neurodevelopmental Disorders  Adrenergic Agents
Mental Disorders  Neurotransmitter Agents
Guanfacine  Molecular Mechanisms of Pharmacological Action
Antihypertensive Agents  Physiological Effects of Drugs
Adrenergic alpha-2 Receptor Agonists