Exploratory fMRI Study on the Treatment for Impulsive Aggression 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: NCT03638466

Recruitment Status : Not yet recruiting
First Posted : August 20, 2018
Last Update Posted : August 21, 2018

See Contacts and Locations

Sponsor:
Supernus Pharmaceuticals, Inc.
Information provided by (Responsible Party):
Supernus Pharmaceuticals, Inc.

Study Details

Tabular View
No Results Posted

Disclaimer
How to Read a Study Record

Study Description

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Brief Summary:
The purpose of this study is to evaluate the effect of 4-week SPN-810 treatment on brain functioning in patients aged 8-12 years with ADHD and associated feature of IA. This will be achieved using functional magnetic resonance imaging (fMRI) in conjunction with the point subtraction aggression paradigm (PSAP) Task, a behavioral aggression paradigm in which subjects are provoked by having money indirectly taken from them by a fictitious opponent, simulating an aggression response.

Condition or disease

Attention Deficit Hyperactivity Disorder (ADHD)

Detailed Description:
Approximately 30 subjects aged 8-12 diagnosed with ADHD and associated feature of IA will be recruited in this study. The PSAP is a behavioral aggression test used to evaluate behavioral response related to impulsive aggression. The task will be combined with functional MRI to evaluate the change in brain activity measured as BOLD signal (blood oxygenation level-dependent) from baseline to the end of the treatment with SPN-810.

The level of neurotransmitters Glutamate and GABA will also be measured using magnetic resonance spectroscopy (MRS).

Additionally, the improvement and severity in impulsive aggression behaviors will be assessed using validated scales.

Study Design

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Study Type : Interventional (Clinical Trial)
Estimated Enrollment: 30 participants
Allocation: Randomized
Intervention Model: Parallel Assignment

Intervention Model Description: A multi-center, double-blind, randomized (1:1), placebo-controlled, parallel-group, 2-arm study

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

Official Title: Exploratory Neuroimaging Study to Evaluate the Effect on Brain Activity of SPN-810 for Impulsive Aggression (IA) in Patients With Attention-Deficit/Hyperactivity Disorder (ADHD) in Conjunction With Standard ADHD Treatment

Estimated Study Start Date: September 10, 2018
Estimated Primary Completion Date: December 31, 2018
Estimated Study Completion Date: December 31, 2018

Resource links provided by the National Library of Medicine
MedlinePlus related topics: Attention Deficit Hyperactivity Disorder
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>Experimental: Single dose of SPN-810</td>
<td>Drug: SPN-810</td>
</tr>
<tr>
<td>Subjects will be treated with medium dose of SPN-810</td>
<td>Single dose of SPN-810</td>
</tr>
<tr>
<td>Placebo Comparator: Placebo</td>
<td>Drug: Placebo</td>
</tr>
<tr>
<td>Subjects will be treated with a matching Placebo</td>
<td>Placebo</td>
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Outcome Measures
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Primary Outcome Measures:

1. BOLD fMRI contrast (beta value) at baseline and after 4 weeks of treatment with SPN-810 in response to the aggression task. The z-score acquired during resting state fMRI before and after the treatment with SPN-810. [Time Frame: 9 weeks]

   BOLD fMRI contrast (neural activation) will be collected during the PSAP behavioral aggression task, while playing the game. The participant will play a computer game in which they can steal points (simulating an aggressive behavior) or have points stolen by the opponent. In addition, imaging data will be collected at resting state to understand the connectivity between regions of interest before and after the aggression task.
Secondary Outcome Measures:

1. Changes in GABA and Glutamate levels from baseline to the end of treatment [Time Frame: 9 weeks]

During the MRI scan, imaging data will be obtained while participants are able to listen to music. GABA and Glutamate signals measured using magnetic resonance spectroscopy (MRS) from two brain regions (anterior cingulate cortex and amygdala) will be used to quantify the two neurotransmitters.

Eligibility Criteria

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: 8 Years to 12 Years (Child)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Otherwise healthy male or female subjects, aged 8-12 years, inclusive, at the time of screening with primary diagnosis of ADHD and currently receiving monotherapy treatment with an optimized US Food and Drug Administration (FDA)-approved ADHD medication.
- Impulsive aggression (IA) will be confirmed at screening using the R-MOAS and the Vitiello Aggression Scale.

Exclusion Criteria:

- Current or lifetime diagnosis of epilepsy, major depressive disorder, bipolar disorder, schizophrenia or related disorder, personality disorder, Tourette's disorder, fetal alcohol syndrome, or psychosis not otherwise specified.
- Currently meeting DSM criteria for autism spectrum disorder, pervasive developmental disorder, obsessive-compulsive disorder, post-traumatic stress disorder.
- Known or suspected IQ <70, pregnancy, substance or alcohol abuse.
- Known history of implanted brain stimulator, vagal nerve stimulator, ventriculoperitoneal shunt, cardiac pacemaker, orthodontic braces, or implanted medication port. Visual and hearing (>25 dB) impairment.
- Pre-existing medical or psychological conditions that preclude being in the MRI scanner (e.g., claustrophobia, morbid obesity, or marked anxiety about the procedure).

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): NCT03638466

Contacts
Contact: Ronald Marcus, MD  301-838-2569  rmarcus@supernus.com
Contact: Gianpiera Ceresoli-Borroni, PhD  301-838-2521  gceresoliborroni@supernus.com

Locations

United States, Florida

Meridien Research aka Florida Clinical Research Center, LLC  Not yet recruiting
Lakeland, Florida, United States, 33805
Contact: Andrew Cutler, MD  863-940-2087  acutler@meridienresearch.net
Florida Clinical Research Center, LLC.  Not yet recruiting
Maitland, Florida, United States, 32751
Contact: Andrea Marraffino, PhD  407-644-1165  amarraffino@flcrc.com
University of South Florida- Dept. of Psychiatry and Neurosciences  Not yet recruiting
Tampa, Florida, United States, 33613
Contact: Daniel Fallon, MD  813-974-2832  dfallon1@health.usf.edu

United States, Maryland

Hugo W Moser Research Institute at Kennedy Krieger  Not yet recruiting
Baltimore, Maryland, United States, 21205
Contact: Robert Findling, MD  443-923-9326  RFindli1@jhmi.edu

Sponsors and Collaborators
Supernus Pharmaceuticals, Inc.

More Information

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Publications:

Responsible Party: Supernus Pharmaceuticals, Inc.
ClinicalTrials.gov Identifier: NCT03638466  History of Changes
Other Study ID Numbers: 810P204
First Posted: August 20, 2018  Key Record Dates
Last Update Posted: August 21, 2018
Last Verified: August 2018

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
Aggression
Attention Deficit and Disruptive Behavior Disorders
Neurodevelopmental Disorders
Mental Disorders

Dyskinesias
Neurologic Manifestations
Nervous System Diseases
Signs and Symptoms
Behavioral Symptoms