Attention-deficit/Hyperactivity Disorder Translational Center for Identifying Biomarkers

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

Verified December 2015 by Seoul National University Childrens Hospital

Sponsor:
Seoul National University Childrens Hospital

Information provided by (Responsible Party):
Booog Nyung Kim, Seoul National University Childrens Hospital

ClinicalTrials.gov Identifier:
NCT02623114

First received: November 29, 2015
Last updated: December 4, 2015
Last verified: December 2015

Purpose

The purpose of this study was to identify genetic, brain morphologic, and environmental biomarkers that contribute to the pathophysiology of attention-deficit/hyperactivity disorder (ADHD).

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attention-deficit/Hyperactivity Disorder</td>
<td>Drug: methylphenidate</td>
<td>Phase 4</td>
</tr>
<tr>
<td></td>
<td>Drug: atomoxetine</td>
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</tbody>
</table>

Study Type: Interventional

Study Design:
Allocation: Non-Randomized
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Comprehensive Pathophysiological Study Based on the Core Neurocognitive Deficits and Development of Biological Markers of Treatment Response in Attention Deficit Hyperactivity Disorder

Resource links provided by NLM:
Further study details as provided by Seoul National University Childrens Hospital:

Primary Outcome Measures:

- Treatment response measured by decrease in ADHD-RS scale [Time Frame: 6 months]
  [Designated as safety issue: No]
Changes in the Parent rated ADHD-Rating Scale - IV (ADHD-RS), which is an 18 item scale, with 9 items assessing inattention and 9 items assessing hyperactivity/impulsivity. It is the most widely used scale to measure symptom severity of attention-deficit/hyperactivity disorder.

- Treatment response measured by CGI-I score [Time Frame: 6 months] [Designated as safety issue: No]
The Clinical Global Impression - Improvement (CGI-I) scale is a clinician rated scale used to measure improvement in symptoms. It ranges from 1 to 7, with 1 meaning very much improved, and 7 meaning very much worse.

- Treatment response measured by changes in CPT score [Time Frame: 6 months] [Designated as safety issue: No]
The continuous performance test (CPT) is an objective measurement of ADHD symptom severity. It is a computerized test and the results are presented in 4 variables: omission errors, commission errors, response time, response time variability.

Secondary Outcome Measures:

- Treatment response measured by decrease in ADHD-RS scale [Time Frame: 1 year]
  [Designated as safety issue: No]
The ADHD-RS scale is described in primary outcome measures.

- Side effects measured using the side effect rating scale (SRS) [Time Frame: 1 year]
  [Designated as safety issue: Yes]
The side effect rating scale (SRS) is a parent rated scale, measuring side effects of multiple domains in the previous 2 week period.

- Treatment response measured by CGI-I score [Time Frame: 1 year] [Designated as safety issue: No]
The CGI-I scale is described in primary outcome measures.

Estimated Enrollment: 400
Study Start Date: May 2012
Estimated Study Completion Date: March 2017
Estimated Primary Completion Date: August 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: Methylphenidate</td>
<td>ADHD patients with methylphenidate administration Generic names include concerta, metadata and penid. The initial dosage was fixed for 2 weeks and then adjusted according to the clinician's judgement. The patients visited the hospital at week 2,4,6,8,16,24, 9months, 12,15,18,21,24 months.</td>
</tr>
<tr>
<td>Drug: methylphenidate</td>
<td>The patients received a fixed dose of medication for 2 weeks. The dose was increased according to the clinician's judgment. The patients came to the hospital at week 2,4,6,8,16,24wks, 9, 12,15,18,21,24 months</td>
</tr>
<tr>
<td>Other Name: concerta, metadata, penid</td>
<td></td>
</tr>
<tr>
<td>Experimental: Atomoxetine</td>
<td>ADHD patients with atomoxetine administration Generic names include strattera. The initial dosage was fixed for 2 weeks and then adjusted according to the clinician's judgement. The patients visited the hospital at week 2,4,6,8,16,24, 9months, 12,15,18,21,24 months.</td>
</tr>
<tr>
<td>Drug: atomoxetine</td>
<td>The patients received a fixed dose of medication for 2 weeks. The dose was increased according to the clinician's judgment. The patients came to the hospital at week 2,4,6,8,16,24wks, 9, 12,15,18,21,24 months</td>
</tr>
<tr>
<td>Other Name: strattera</td>
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</tbody>
</table>

**Detailed Description:**

The investigators planned to recruit ADHD and healthy controls from the age of 6 to 17.

Genetic data including dopamine, norepinephrine, serotonin, neurotropic factors, glutamate-related genes will be genotyped.

Environmental disruptors including phthalate and cotinine will be analyzed. Brain MRI data including T1, diffusion tensor imaging (DTI), resting state functional MRI (rsfMRI) will be obtained.

Neuropsychological tests including continuous performance test, Stroop test, Children’s color trail test, Wisconsin card sorting test will be conducted.

The investigators plan to identify biomarkers of ADHD using an integrative approach of genetic, environmental, neuroimaging and clinical data.

**Eligibility**

- Ages Eligible for Study: 6 Years to 17 Years
- Genders Eligible for Study: Both
- Accepts Healthy Volunteers: Yes

**Criteria**

**Inclusion Criteria:**

- IQ over 70
Exclusion Criteria:

- Intelligence quotient (IQ) < 70
- A hereditary genetic disorder
- A current/past history of brain trauma, organic brain disorder, seizure, or any neurological disorder
- Autism spectrum disorder, communication disorder, or learning disorder
- Schizophrenia or any other childhood-onset psychotic disorder
- Major depressive disorder or bipolar disorder
- Tourette's syndrome or chronic motor/vocal tic disorder
- Obsessive-compulsive disorder
- A history of methylphenidate treatment lasting more than 1 year or received within the previous 4 weeks

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: NCT02623114

Contacts

Contact: Johanna IH Kim, MD  iambabyvox@hanmail.net

Locations

Korea, Republic of

Seoul National University Children's Hospital  Recruiting
Seoul, Korea, Republic of
Contact: Johanna Kim, MD

Sponsors and Collaborators

Seoul National University Childrens Hospital

Investigators

Principal Investigator:  Boong-nyung Kim, MD, PhD  Seoul National University Hospital

More Information

No publications provided

Responsible Party:  Boog Nyung Kim, Professor, Seoul National University Childrens Hospital

ClinicalTrials.gov Identifier:  NCT02623114  History of Changes

Other Study ID Numbers:  0720151002

Study First Received:  November 29, 2015

Last Updated:  December 4, 2015

Health Authority:  Korea: Ministry for Health and Welfare
Additional relevant MeSH terms:
Attention Deficit Disorder with Hyperactivity  Adrenergic Uptake Inhibitors
Hyperkinesis  Central Nervous System Agents
Attention Deficit and Disruptive Behavior Disorders  Central Nervous System Stimulants
Dyskinesias  Dopamine Agents
Mental Disorders  Dopamine Uptake Inhibitors
Mental Disorders Diagnosed in Childhood  Molecular Mechanisms of Pharmacological Action
Nervous System Diseases  Neurotransmitter Agents
Neurologic Manifestations  Neurotransmitter Uptake Inhibitors
Signs and Symptoms  Pharmacologic Actions
Atomoxetine  Physiological Effects of Drugs
Methylphenidate  Therapeutic Uses
Adrenergic Agents

ClinicalTrials.gov processed this record on December 04, 2015