A Noninterventional Genotype/Phenotype Study of mGluR Mutations in Children and Adolescents With ADHD

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

Verified June 2016 by Medgenics, Inc.

Sponsor:
Medgenics, Inc.

Information provided by (Responsible Party):
Medgenics, Inc.

ClinicalTrials.gov Identifier:
NCT02811211

First received: June 21, 2016
Last updated: NA
Last verified: June 2016
History: No changes posted

Purpose

This noninterventional study will assess genomic changes in the metabotropic glutamate receptor (mGluR) network in children and adolescents with ADHD.

<table>
<thead>
<tr>
<th>Condition</th>
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<td>Attention Deficit Disorder With Hyperactivity</td>
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Study Type: Observational

Study Design: Observational Model: Case-Only
Time Perspective: Cross-Sectional

Official Title: A Noninterventional Genotype/Phenotype Study of mGluR Mutations in Children and Adolescents With Attention Deficit Hyperactivity Disorder (ADHD)

Resource links provided by NLM:

MedlinePlus related topics: Attention Deficit Hyperactivity Disorder
Further study details as provided by Medgenics, Inc.:

Primary Outcome Measures:

- Presence of mGluR network mutations [Time Frame: At study enrollment] [Designated as safety issue: No]

Biospecimen Retention: Samples With DNA
Saliva

Estimated Enrollment: 1500

Study Start Date: February 2016

Estimated Study Completion Date: February 2017

Estimated Primary Completion Date: February 2017 (Final data collection date for primary outcome measure)

Detailed Description:

Male and female subjects 6 to 17 years of age with a primary psychiatric diagnosis of ADHD will be enrolled in this study. The subject and his or her parent/guardian must agree to genotyping to determine whether the subject has disruptive mutations within any of the approximately 274 mGluR-network genes, and complete an interview that will include information about the subject's ADHD history, treatment, and co-morbidities.

Eligibility

Ages Eligible for Study: 6 Years to 17 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No
Sampling Method: Non-Probability Sample

Study Population

Subjects between the ages of 6 years and 17 years of age with a previously established diagnosis of ADHD will be eligible for screening.

Criteria

Inclusion Criteria:

- The subject is male or female ≥6 and ≤17 years of age.
- The subject has ADHD as defined by the Diagnostic and Statistical Manual of Mental Disorders, 5th edition.
- The subject, his or her legally responsible representative, and investigator agree to complete ADHD history, treatment, and comorbidity electronic case report form (eCRF).

Exclusion Criteria:

- The subject or parent/legal guardian is in the opinion of the investigator mentally or legally incapacitated and unable to provide informed consent/assent for participation in the study.

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
Please refer to this study by its ClinicalTrials.gov identifier: NCT02811211

Contacts
Contact: Medgenics

Locations

United States, Delaware
A.I. DuPont Hospital for Children Recruiting Wilmington, Delaware, United States, 19803 Contact: Josephine Elia, MD 302-651-4000

Sponsors and Collaborators
Medgenics, Inc.

Investigators
Study Director: Liza Squires, M.D. Medgenics, Inc.

More Information

Responsible Party: Medgenics, Inc.
ClinicalTrials.gov Identifier: NCT02811211 History of Changes
Other Study ID Numbers: MDGN-NFC1-ADHD-001
Study First Received: June 21, 2016
Last Updated: June 21, 2016
Health Authority: United States: Institutional Review Board

Additional relevant MeSH terms:
Attention Deficit Disorder with Hyperactivity Nervous System Diseases
Hyperkinesis Neurodevelopmental Disorders
Attention Deficit and Disruptive Behavior Disorders Neurologic Manifestations
Dyskinesias Signs and Symptoms
Mental Disorders

ClinicalTrials.gov processed this record on June 22, 2016