Long-term Effects of Medication for ADHD (LMA)

This study is currently recruiting participants.

Verified August 2017 by Göteborg University

Sponsor: Göteborg University

Information provided by (Responsible Party): Göteborg University

ClinicalTrials.gov Identifier: NCT03250013

First received: August 4, 2017
Last updated: August 14, 2017
Last verified: August 2017

Purpose

Single-centre open-label prospective study, enrolling 100 children and adolescents aged 6-17 years, who receive medication for ADHD of any subtype (presentation). Long-term results are evaluated with tests of ADHD symptoms (Qb-test), intellectual ability (Wechsler scales; WISC), adaptive functioning (Vineland scale), everyday functioning (Weiss Functional Impairment Scale; WIFRS), and quality of life (Child Health and Illness Profile-Child Edition Scale; CHIP-CE) during 24 months of ADHD treatment.

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

Study Design: Observational Model: Cohort

Time Perspective: Prospective

Official Title: Long-term Effects of Medication for Attention Deficit Hyperactivity Disorder (ADHD) in Children and Adolescents on Cognition, Everyday Function and Quality of Life

Resource links provided by NLM:

MedlinePlus related topics: Attention Deficit Hyperactivity Disorder
Further study details as provided by Göteborg University:

Primary Outcome Measures:
- Change in CGI - (S and I) [ Time Frame: 0, 1, 2, 3, 6, 12, 18 and 24 months ]
  Investigator-rated clinical global impression scale - severity and improvement

Secondary Outcome Measures:
- ADHD Rating Scale [ Time Frame: 0, 1, 2, 3, 6, 12, 18 and 24 months ]
  Clinician-rated ADHD symptom scale
- Qb-test [ Time Frame: 0, 1 and 12 months ]
  Computerized ADHD-test
- WISC-IV [ Time Frame: 0 and 12 months ]
  Wechsler Intelligence Scale for Children
- Vineland scale [ Time Frame: 0 and 12 months ]
  Vineland parent interview of functioning
- Weiss Functional Impairment Scale (WFIRS) [ Time Frame: 0, 12 and 24 months ]
  Parent-rated function scale
- Child Health and Illness Profile - Child Edition (CHIP-CE) [ Time Frame: 0, 12 and 24 months ]
  Parent-rated quality of life scale

Estimated Enrollment: 100
Study Start Date: April 2014
Estimated Study Completion Date: December 2019
Estimated Primary Completion Date: December 2019 (Final data collection date for primary outcome measure)

<table>
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<th>Groups/Cohorts</th>
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<tbody>
<tr>
<td>Children and adolescents with ADHD</td>
</tr>
<tr>
<td>Children and adolescents medicating for ADHD of any subtype (presentation) with comorbidities</td>
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</table>
Detailed Description:

Single-centre open-label prospective study, including 100 subjects over a period of 2 years. Children and adolescents (6-17 years) who have been diagnosed with ADHD will be enrolled and followed during 24 months of ADHD treatment.

Screening assessments include medical, neurodevelopmental and psychiatric history, clinical evaluation and definition of the ADHD diagnosis and its subtypes or presentations (according to Diagnostic and Statistical Manual (DSM) IV and DSM 5), ADHD symptom severity and global functional impairment (by the investigator-rated ADHD Rating Scale-IV (ADHD-RS-IV) and Clinical Global Impression Scale-Severity and Improvement; CGI-S and CGI-I), comorbidities (by the Kiddie Schedule for Affective Disorders and Schizophrenia (K-SADS) clinical interview), intellectual ability (by the WISC-IV test), and general level of functioning (by the Vineland interview). Subjects previously assessed and diagnosed will be re-assessed at the screening visit to ascertain a current evaluation and definition of these parameters.

At baseline, a Qb-test and an assessment of symptom severity and global functional impairment will be made by the investigator-rated ADHD-RS-IV and CGI-S, everyday functioning by parent-rated WIFRS, and quality of life by parent-rated CHIP-CE. An adverse events report will be collected by interview with open-ended questions. Assignment to treatment will be individualized according to clinical picture and patient preference.

At subsequent visits (1, 2, 3, 6, 12, 18 and 24 months) the following assessments will be performed: Investigator-rated ADHD-RS-IV, CGI-S, Clinical Global Impression-Improvement (CGI-I) scales for symptom severity, global functional impairment and improvement. Adverse event report. Compliance assessment through pill count. Assessment of comorbidity status according to DSM-IV and DSM 5 checklist/interview.

A Qb-test will be performed at the 1 and 12 month visits. Everyday functioning and quality of life will be assessed by parent-rated WIFRS and CHIP-CE scales at the 12 and 24 month visits.

Duration of study treatment per subject is 24 months. Medication dosage is 1-3 doses daily as needed to optimize symptom control. Medications (methylphenidate, amphetamine, atomoxetine) will be provided by the pharmacy according to routines in standard clinical treatment.

For cluster analysis of Qb-test results, retrospective data from at least 50 patients previously diagnosed at our clinic will be added to the data from the subjects participating in the prospective study, to increase sample size to ascertain sufficient power for subgroup (cluster) analysis.

Safety evaluations Adverse event (AE) reports will be collected at all visits through open-ended questions. Vital signs (height, weight, blood pressure, pulse) will be assessed at all visits. AE severity should be graded: Mild, Moderate or Severe, and all AEs must be followed until an outcome is known, ensuring the subject's safety. All AEs will be recorded in the subject's medical records and in the Clinical Report Form (CRF), and also reported to the Medical Products Agency according to local regulations.

Study population Approximately 100 subjects from our centre will be enrolled in the prospective study.

Retrospective data for the cluster analysis will be collected from at least 50 patients previously diagnosed at our centre.

Eligibility

Ages Eligible for Study: 6 Years to 17 Years (Child)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No
Sampling Method: Probability Sample

**Study Population**
Children and adolescents with ADHD

**Criteria**

**Inclusion Criteria:**
1. Children 6-17 years of age
2. Clinical diagnosis ADHD of any subtype and DSM 5 presentation
3. Intellectual ability in the normal range, according to Wechsler tests and clinical judgment
4. Subjects treated with ADHD medication will have a wash-out period prior to Qb-test at baseline, of 1 week for methylphenidate or amphetamine, 2 weeks for atomoxetine

**Exclusion Criteria:**
1. Physical or psychological limitation making Qb-test unsuitable.
2. Cardiovascular disease, seizures or other unstable medical conditions that might increase the risk for the subject.
3. Bipolar Disorder, Conduct Disorder, Psychosis, severe autism or other severe comorbid or medical conditions that in the investigator's opinion would make study participation unsuitable.
4. Concomitant medications (allowed at investigator's discretion), must be recorded in the subject's medical records and the CRF.
5. Substance abuse.

**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: NCT03250013

**Contacts**
Contact: Mats Johnson, MD, PhD  +4631-3425951  mats.johnson@gnc.gu.se
Contact: Klara Jakobsson, Study nurse  031-3425967  klara.jakobsson@vgregion.se

**Locations**

**Sweden**

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Gothenburg, Sweden, 41118  
Contact: Klara Jakobsson, Study nurse  +4631-3425967  klara.jakobsson@vgregion.se

**Sponsors and Collaborators**

Göteborg University

**Investigators**

Principal  Mats Johnson, MD,  Child Neuropsychiatry Unit, Sahlgrenska University Hospital,
Investigator: PhD Gothenburg, Sweden

Responsible Party: Göteborg University

ClinicalTrials.gov Identifier: NCT03250013

Other Study ID Numbers: LMA trial Goteborg

Study First Received: August 4, 2017

Last Updated: August 14, 2017

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

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

ClinicalTrials.gov processed this record on August 15, 2017