Network Connectivity and Inhibitory Control Under Atomoxetin Challenge- A Pharmacological 'Resting State' and 'Inhibiton Task' Study in Patients With ADHD (CAIAC)

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: NCT03661788

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

Sponsor:
RWTH Aachen University

Information provided by (Responsible Party):
RWTH Aachen University

Study Description

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Brief Summary:

Attention deficit /hyperactivity disorder (ADHD) is a disorder which manifests in childhood but often persists through adulthood. The most prominent symptoms in adults are inattention, emotional instability, disorganized behavior, impulsivity and restlessness, which cause several restrictions in different areas of life. It is suggested that those symptoms can be attributed to a general deficit in inhibitory control. This hypothesis is supported by several studies revealing that patients with ADHD show poor performance completing inhibitory control tasks.

Furthermore, studies showed that a unique administration of atomoxetin (ATX) significantly improves inhibitory control in patients with ADHD as well as in healthy participants. In contrast to other medication authorized for the treatment of patients with ADHD, does ATX has no risk for potential addiction. Due its indirect mode of action, ATX has a delayed effect occurrence taking up to 2 weeks. However, this aspect was unconsidered in those studies.

Although we directly often associate failures in cognitive control with disruptions at prefrontal areas of the brain, there exists a specific brain network which is called the default mode network (DMN), which is suggested to be at least partly responsible for the ADHD symptomatic.

The following study is interested in which way a 2- week intake of ATX affects the DMN and surrounding networks in their connectivity during a inhibitory control task and during rest in patients with ADHD vs controls.

<table>
<thead>
<tr>
<th>Condition or disease</th>
<th>Drug</th>
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<tbody>
<tr>
<td>ADHD</td>
<td>AtomoxetineDrug: Placebos</td>
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Study Design

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**Study Type**: Interventional (Clinical Trial)

**Actual Enrollment**: 38 participants

**Allocation**: Randomized

**Intervention Model**: Crossover Assignment

**Masking**: Triple (Participant, Care Provider, Investigator)

**Primary Purpose**: Health Services Research

**Study Start Date**: May 2016

**Actual Primary Completion Date**: December 6, 2017

**Actual Study Completion Date**: June 27, 2018

**Resource links provided by the National Library of Medicine**

Drug Information available for: Atomoxetine hydrochloride, Atomoxetine

U.S. FDA Resources

### Arms and Interventions

<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention/treatment</th>
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</table>
| Experimental: First placebo, than atomoxetine  
Patients receive a placebo in the first of the two 14-day treatment intervals and atomoxetine in the second 14-day treatment intervals. Between the treatment intervals there is a wash-out phase of two weeks. The order of treatment is randomized. | Drug: Atomoxetine  
14-day treatment interval: first week 40 mg atomoxetine (one pill), second week 80 mg atomoxetine (two pills)  
Other Name: Strattera  
Drug: Placebos  
14-day treatment interval: first week one placebo pill, second week two placebo pills |
| Experimental: First atomoxetine, than placebo  
Patients receive atomoxetine in the first of the two 14-day treatment intervals and a placebo in the second 14-day treatment interval. Between the treatment intervals there is a wash-out phase of two weeks. The order of treatment is randomized. | Drug: Atomoxetine  
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### Outcome Measures

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**Primary Outcome Measures**:

1. FMRT resting state connectivity of the default mode network [Time Frame: 4 weeks]

### Eligibility Criteria
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:** 18 Years to 45 Years (Adult)

**Sexes Eligible for Study:** Female

**Accepts Healthy Volunteers:** No

**Criteria**

**Inclusion Criteria:**
- Male Age 18-45 years Diagnosis of ADHD (patients) or no axis I disorder (controls) according the DSM IV
- No substance abuse/dependency
- Understanding of the study information and declaration of agreement
- Ability to read, understand and speak German
- No severe medical disorders
- No risk for suicide

**Exclusion Criteria:**
- Drug dependence or the a positive drug screening
- Other severe physical disorders
- Current pharmacological therapy because of another psychiatric disorder
- Risk for seizure or cardiac problems
- Impaired liver and renal function
- Significant deviations in regard to clinical chemistry, haematology or EKG
- Relationship of dependency with the sponsor or the investigator
- Unable to keep to the study protocol
- Known Intolerance of the study medication
- fMRI scanner incompatibility

**Contacts and Locations**

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): **NCT03661788**

**Locations**

**Germany**

University Hospital RWTH Aachen
Aachen, Germany, 52074

**Sponsors and Collaborators**

RWTH Aachen University

**More Information**

Responsible Party: RWTH Aachen University

ClinicalTrials.gov Identifier: NCT03661788  History of Changes

Other Study ID Numbers: 11-185 CAIAC
2013-002386-18 (EudraCT Number)

First Posted: September 7, 2018  Key Record Dates

Last Update Posted: September 7, 2018

Last Verified: September 2018
Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: Yes

Plan Description: Data will be uploaded into the data pool of the Deutsches Netzwerk zu psychischen Erkrankungen.

Keywords provided by RWTH Aachen University:
Atomoxetine
fMRT

Additional relevant MeSH terms:
Atomoxetine Hydrochloride
Adrenergic Uptake Inhibitors
Neurotransmitter Uptake Inhibitors
Membrane Transport Modulators

Molecular Mechanisms of Pharmacological Action
Adrenergic Agents
Neurotransmitter Agents
Physiological Effects of Drugs