Oxytocin and Cognitive Control in Adult ADHD

This study is not yet open for participant recruitment. (see Contacts and Locations)

Verified April 2017 by Massachusetts General Hospital

Sponsor:
Massachusetts General Hospital

Information provided by (Responsible Party):
Elizabeth Austen Lawson, Massachusetts General Hospital

ClinicalTrials.gov Identifier:
NCT03136263

First received: April 26, 2017
Last updated: April 27, 2017
Last verified: April 2017

Purpose
This is a randomized, double-blind, placebo-controlled crossover study of single-dose intranasal oxytocin (24 IU) in 18-55 year-old men with attention deficit/hyperactivity disorder (ADHD). Following a screening visit to determine eligibility, subjects will return for two main study visits. During the main study visits, study participants will receive either oxytocin (Syntocinon® nasal spray, Victoria Pharmacy, Zürich, Switzerland) or placebo (inactive ingredients of Syntocinon® nasal spray, Victoria Pharmacy), followed by assessments of cognitive control over attention and behavior. Twenty-four participants will be randomized 1:1 to one of two drug orders, i.e., oxytocin - placebo or placebo - oxytocin. In an additional neuroimaging substudy, a subset of participants will undergo task-based and resting-state functional magnetic resonance imaging (fMRI) following oxytocin/placebo administration to investigate the effects of oxytocin on fMRI activation and functional connectivity within the cognitive control network.

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<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
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| Attention Deficit/Hyperactivity Disorder | Drug: Oxytocin nasal spray  
Drug: Placebo nasal spray | Early Phase 1 |

Study Type: Interventional

Study Design: Allocation: Randomized  
Intervention Model: Crossover Assignment
Masking: Participant, Investigator, Outcomes Assessor
Primary Purpose: Basic Science

Official Title: Effects of Oxytocin on Cognitive Control in Adults With Attention Deficit/Hyperactivity Disorder

Resource links provided by NLM:

MedlinePlus related topics: Attention Deficit Hyperactivity Disorder
Drug Information available for: Oxytocin
U.S. FDA Resources

Further study details as provided by Massachusetts General Hospital:

Primary Outcome Measures:

- Stop-signal task [Time Frame: First and second main study visits (1-4 weeks apart)]
  Mean difference in performance on the stop-signal task between the oxytocin and placebo visits (stop-signal reaction time)

Secondary Outcome Measures:

- AX-CPT [Time Frame: First and second main study visits (1-4 weeks apart)]
  Mean difference in performance on the AX-CPT between the oxytocin and placebo visits (AY responses)

- Category switch task [Time Frame: First and second main study visits (1-4 weeks apart)]
  Mean difference in performance on the category switch task between the oxytocin and placebo visits (switch costs)

- Global/local task [Time Frame: First and second main study visits (1-4 weeks apart)]
  Mean difference in performance on the global/local task between the oxytocin and placebo visits (global precedence effect)

- Simon task [Time Frame: First and second main study visits (1-4 weeks apart)]
  Mean difference in performance on the Simon task between the oxytocin and placebo visits (Simon effect and Garner effect)

Estimated Enrollment: 24
Anticipated Study Start Date: May 2017

Estimated Study Completion Date: May 2019

Estimated Primary Completion Date: May 2019 (Final data collection date for primary outcome measure)

<table>
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<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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</table>
| Experimental: Drug order: Oxytocin - placebo | Drug: Oxytocin nasal spray  
Single-dose intranasal oxytocin (24 IU; Syntocinon® nasal spray, Victoria Pharmacy, Zürich, Switzerland)  
Drug: Placebo nasal spray  
Single-dose intranasal placebo (inactive ingredients of Syntocinon® nasal spray, Victoria Pharmacy, Zürich, Switzerland) |
| Experimental: Drug order: Placebo - oxytocin | Drug: Oxytocin nasal spray  
Single-dose intranasal oxytocin (24 IU; Syntocinon® nasal spray, Victoria Pharmacy, Zürich, Switzerland)  
Drug: Placebo nasal spray  
Single-dose intranasal placebo (inactive ingredients of Syntocinon® nasal spray, Victoria Pharmacy, Zürich, Switzerland) |

▶ Eligibility

Ages Eligible for Study: 18 Years to 55 Years (Adult)

Sexes Eligible for Study: Male

Accepts Healthy Volunteers: No

Criteria

Inclusion criteria:

- Male
- 18-55 years
- Diagnosis of attention deficit/hyperactivity disorder

Exclusion criteria:

- History of cardiovascular disease (e.g., hypertrophic cardiomyopathy, valvular heart disease, coronary heart disease, or coronary artery spasms)
- History of diabetes mellitus
- Untreated thyroid disease
- Hematocrit below the normal range
- Tobacco use
Any other significant illness that the investigator determines could interfere with study participation or safety or put the subject at any unnecessary risk

**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: NCT03136263

**Contacts**

Contact: Franziska Plessow, Ph.D. 617-726-0784 fplessow@mgh.harvard.edu

**Sponsors and Collaborators**

Massachusetts General Hospital

**Investigators**

Principal Investigator: Elizabeth A. Lawson, M.D., M.M.Sc. Massachusetts General Hospital

**More Information**

Responsible Party: Elizabeth Austen Lawson, Assistant Professor of Medicine, Massachusetts General Hospital

ClinicalTrials.gov Identifier: NCT03136263  History of Changes

Other Study ID Numbers: 2017P000123

Study First Received: April 26, 2017

Last Updated: April 27, 2017

Individual Participant Data

Plan to Share IPD: No

Studies a U.S. FDA-regulated Drug Product: Yes

Studies a U.S. FDA-regulated Device Product: No

Keywords provided by Massachusetts General Hospital:

Attention  Executive functions
Attention deficit/hyperactivity disorder  Impulse control
Cognitive control  Impulsivity
Executive control  Oxytocin
Additional relevant MeSH terms:

- Attention Deficit Disorder with Hyperactivity
- Hyperkinesis
- Attention Deficit and Disruptive Behavior Disorders
- Neurodevelopmental Disorders
- Mental Disorders
- Dyskinesias
- Neurologic Manifestations

Nervous System Diseases
Signs and Symptoms
Oxytocin
Oxytocics
Reproductive Control Agents
Physiological Effects of Drugs

ClinicalTrials.gov processed this record on May 02, 2017