Treatment of Cannabis Use Disorder Among Adults With Comorbid Attention-Deficit/Hyperactivity Disorder (MJ-ADHD)

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

Verified June 2016 by New York State Psychiatric Institute

Sponsor:
New York State Psychiatric Institute

Collaborator:
National Institute on Drug Abuse (NIDA)

Information provided by (Responsible Party):
New York State Psychiatric Institute

ClinicalTrials.gov Identifier:
NCT02803229

First received: June 9, 2016
Last updated: June 13, 2016
Last verified: June 2016

History of Changes

Purpose
The proposed protocol is a double-blind, placebo-controlled outpatient study of the safety and benefit of Extended-release mixed amphetamine salt (Adderall-XR, MAS-XR) in the treatment of individuals with Cannabis Use Disorder (CUD) and Attention-deficit/Hyperactivity Disorder (ADHD). The investigators plan to enroll 50 and randomize 40 of these patients in the trial. The primary objective of the study is to determine the efficacy of MAS-XR in promoting cannabis abstinence among individuals with CUD and in promoting a decrease of ADHD symptoms.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cannabis Use Disorder</td>
<td>Drug: Adderall-XR</td>
<td>Phase 2</td>
</tr>
<tr>
<td>Attention-deficit/Hyperactivity Disorder</td>
<td>Other: Matched placebo</td>
<td>Phase 3</td>
</tr>
</tbody>
</table>

Study Type: Interventional

Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: Treatment of Cannabis Use Disorder Among Adults With Comorbid Attention-Deficit/Hyperactivity Disorder

Resource links provided by NLM:

MedlinePlus related topics: Attention Deficit Hyperactivity Disorder Marijuana

U.S. FDA Resources

Further study details as provided by New York State Psychiatric Institute:

Primary Outcome Measures:

- Marijuana abstinence [ Time Frame: last two weeks of the 12 week study on maintained dose (weeks 10 and 11 for completers) or last two weeks of participants' participation during the 12 week study ]
  [ Designated as safety issue: No ]
  defined as abstinence from marijuana during the last two weeks of the trial as recorded by the Timeline Followback method and confirmed by urine toxicology.

- Reduction in ADHD symptoms [ Time Frame: last week of trial on maintained dose during the 12 week trial (week 11 for completers) or last week of participants' participation during the 12 week trial ]
  [ Designated as safety issue: No ]
  The primary ADHD outcome measure will be the percentage of individuals who achieve at least a 30% reduction in symptom severity as measured by the Adult ADHD Interview Rating Scale (AISRS).

Estimated Enrollment: 50

Study Start Date: June 2016

Estimated Study Completion Date: September 2018

Estimated Primary Completion Date: June 2018 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo Comparator: Placebo matched Placebo arm</td>
<td>Other: Matched placebo matched placebo provided for placebo arm</td>
</tr>
<tr>
<td>Experimental: Adderall-XR Adderall-XR (MAS-XR) 80 mg/day maximum maintenance dose</td>
<td>Drug: Adderall-XR Other Name: Extended-release mixed amphetamine salt</td>
</tr>
</tbody>
</table>
Detailed Description:

ADHD is common in substance use disorder patients in general and cannabis use disorder (CUD) in particular, occurring at rates substantially greater than in the general population. A meta-analysis found that approximately 23% of substance abusers seeking treatment have childhood and/or adult ADHD. Moreover, ADHD was overrepresented in adults with CUD compared to other substance use disorder patients seeking treatment. The importance in treating CUD individuals who also have ADHD is underscored by findings demonstrating that individuals with co-occurring ADHD and substance use disorders are a particularly intractable group: they exhibit earlier onset of use, more severe use, a more complicated pattern of remission/relapse, and poorer treatment outcomes relative to those without ADHD. Yet, to date, ADHD individuals with CUD have not been adequately studied. The investigators have found that in their treatment research studies targeting cannabis dependence that a substantial percentage (35%) have screened positive for adult ADHD, rates that are higher than participants in their cocaine use disorder clinical trial and almost 8x greater than rates found in the general population. Thus, this appears to be a sizable cannabis-abusing group warranting much greater clinical attention than they are currently receiving.

The goal is to demonstrate feasibility, tolerability, and estimate effect size for purposes of planning future more definitive trials. Because of the research team's extensive experience in working with stimulant medication in treating ADHD in cocaine-dependent populations, the large effect size of amphetamine in treating adult ADHD, and notable reduction in cocaine use and ADHD symptoms in cocaine-dependent ADHD adults, the investigators will explore the efficacy of Adderall-XR (MAS-XR) for the treatment of cannabis use disorder and ADHD. The study is a 12 week placebo controlled double-blind trial. The maximum maintained dose will be 80 mg of MAS-XR daily.

Eligibility

Ages Eligible for Study: 18 Years to 65 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Individuals who meet criteria for cannabis use disorder (CUD) and report that marijuana is their primary drug of abuse
- Individuals must report using marijuana at least 5 days a week and have a positive urine test for THC on the day of study entry
- Individuals must meet DSM-5 criteria for adult ADHD
- Individuals who score > 22 on the AISRS scale
- Individuals between the ages of 18-65 capable of giving informed consent and capable of complying with study procedures
- Women of child-bearing age will be included if they: a) are not pregnant, b) agree to use an effective method of contraception, c) agree not to become pregnant during the study and d) are not breastfeeding. To confirm this, urine pregnancy tests will be repeated every month after screening. Women will be provided a full explanation of the potential dangers of pregnancy while taking MAS-XR. If a woman becomes pregnant, she will be taken off medication and continue standard treatment at STARS. At the end of the study, patients will be offered treatment at STARS until an appropriate referral can be made to a community clinic.
Exclusion Criteria:

- Individuals meeting DSM-5 criteria for schizophrenia, schizoaffective illness, psychotic disorder other than transient psychosis due to drug abuse, current major depression, bipolar illness or psychiatric disorders (other than substance abuse) which require psychiatric intervention or would interfere with study participation

- Individuals who are medically unstable based on laboratory tests, electrocardiogram, medical history, physical examination that would make participation hazardous

- Use of synthetic cannabinoids in the past month and meeting CUD diagnosis based on synthetic cannabinoids use alone in the past year

- Individuals with liver enzyme function tests greater than 3 times normal

- Individuals with significant current suicidal risk

- Individuals with systolic blood pressure > 140; diastolic blood pressure > 90; pulse > 100

- Individuals who are cognitively impaired to impede study participation

- Nursing mothers and pregnant women

- Individuals who are physiologically dependent on any other drugs (excluding nicotine) that would require a medical intervention

- Individuals with known sensitivity/allergy to MAS-XR or amphetamine analogs

- Individuals currently being prescribed psychotropic medication (including sleep medication)

- Individuals with history of seizures

- Individuals who are mandated to treatment

- Individuals with a history of amphetamine use disorders, including amphetamines such as methamphetamine and MDMA.

- Individuals with a current cocaine use disorder

**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: NCT02803229

**Contacts**

Contact: Amy Mahony, LMHC  646-774-8183  mahonya@nyspi.columbia.edu

Contact: Elizabeth Martinez  212-923-3031

**Sponsors and Collaborators**

New York State Psychiatric Institute
National Institute on Drug Abuse (NIDA)

**Investigators**

Principal Investigator:  Frances R Levin, MD  New York Psychiatric Institute
Responsible Party: New York State Psychiatric Institute

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Other Study ID Numbers: 7280  U54DA037842-01

Study First Received: June 9, 2016

Last Updated: June 13, 2016

Health Authority: United States: Food and Drug Administration

Additional relevant MeSH terms:

Attention Deficit Disorder with Hyperactivity
Hyperkinesis
Marijuana Abuse
Attention Deficit and Disruptive Behavior Disorders
Chemically-Induced Disorders
Dyskinesias
Mental Disorders
Nervous System Diseases

Neurodevelopmental Disorders
Neurologic Manifestations
Pathologic Processes
Signs and Symptoms
Substance-Related Disorders
Adderall
Central Nervous System Stimulants
Physiological Effects of Drugs

ClinicalTrials.gov processed this record on June 15, 2016