Effectiveness of Methylphenidate Late Formula to Reduce Cannabis Use in Young Cannabis-Related Patients and Attention Deficit Disorder Hyperactivity (METHACAN)

ClinicalTrials.gov Identifier: NCT03481959

Recruitment Status : Not yet recruiting
First Posted : March 29, 2018
Last Update Posted : March 29, 2018
See **Contacts and Locations**

Sponsor:
Assistance Publique - Hôpitaux de Paris
Information provided by (Responsible Party):
Assistance Publique - Hôpitaux de Paris

Study Description

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Brief Summary:

Abuse of psychoactive substances is a behavior belonging to the field of risk behaviors that begins and takes place during adolescence. These risk behaviors are a major public health problem in France and worldwide.

Cannabis is the first illicit drug consumed by adolescents in France. His experimentation progresses rapidly between 11 and 17 years. The relationship between cannabis use and mental health has been shown by several studies. In particular Attention Deficit Hyperactivity Disorder (ADHD), characterized by attention deficit, impulsivity and disabling motor hyperactivity and beginning before 12 years of age (DSM-5), is a major risk factor for the consumption of cannabis. ADHD is a common condition (9% of children and 5% of adults), but often undiagnosed or untreated. It has been shown that the treatment of ADHD in childhood protects the consumption of psychoactive products during adolescence or adulthood. However, to our knowledge there is no study showing that treatment with methylphenidate in an ADHD patient - not treated - but already a cannabis user, was a positive prognostic factor in the decrease in cannabis use.

Condition or disease	Intervention/treatment
Attention Deficit Hyperactivity Disorder (ADHD)	Drug: MethylphenidateOther: Matching Placeb

Detailed Description:

Abuse of psychoactive substances is a behavior belonging to the field of risk behaviors that begins and takes place during adolescence. These risk behaviors are a major public health problem in France and worldwide.

Cannabis is the first illicit drug consumed by adolescents in France. His experimentation progresses rapidly between 11 and 17 years. The relationship between cannabis use and mental health has been shown by several studies. In particular Attention Deficit Hyperactivity Disorder (ADHD), characterized by attention deficit, impulsivity and disabling motor hyperactivity and beginning before 12 years of age (DSM-5), is a major risk factor for the consumption of cannabis. ADHD is a common condition (9% of children and 5% of adults), but often undiagnosed or untreated. It has been shown that the treatment of ADHD in childhood protects against the use of cannabis during adolescence or adulthood. However, to our knowledge there is no study showing that treatment with methylphenidate in an ADHD patient - not treated - but already a cannabis user, was a positive prognostic factor in the decrease in cannabis use.

Hypothesis: The hypothesis of this study is that patients diagnosed with ADHD and cannabis-treated patients treated with methylphenidate will decrease their number of days of cannabis use compared to ADHD patients receiving placebo.

Originality and Innovative To our knowledge, there is no study showing that treatment with methylphenidate in an ADHD patient - not treated - but already a problematic cannabis user, was a positive prognostic factor in decreasing cannabis use.

Moreover, there is not enough team in addiction trained in the detection of attention deficit disorder which is now recognized as a factor of vulnerability for the development of addictions. This project is the opportunity for a training in the detection of the ADHD in the adolescent and the young adult of the professionals of the addiction and the setting up of a treatment by Methylphenidate as well as its handling.

Study Design

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Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	70 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Double (Participant, Investigator)
Primary Purpose:	Treatment
Official Title:	Effectiveness of Methylphenidate Late Formula to Reduce Cannabis Use in Young Cannabis-Related Patients and Attention Deficit Disorder Hyperactivity
Anticipated Study Start Date :	November 5, 2018
Estimated Primary Completion Date :	November 5, 2021
Estimated Study Completion Date :	November 5, 2021

Resource links provided by the National Library of Medicine

MedlinePlus related topics: Attention Deficit Hyperactivity Disorder Marijuana

Drug Information available for: Methylphenidate Methylphenidate hydrochloride

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Experimental: Methylphenidate	Drug: Methylphenidate

Methylphenidate delay shape, 10 and 30 mg capsules. Treatment should be started at a dose of 10 mg per day or 20 mg/d (depending on the weight of patients), with increasing weekly, according to the clinical tolerance, in order to get an effective dose on the symptoms of ADHD to S4, not more than 1 mg/kg/d (capped at 60 mg/d).	Methylphenidate delay shape, 10 and 30 mg and matching Placebo capsules. Treatment should be started at a dose of 10 mg per day or 20 mg/d (depending on the weight of patients), with increasing weekly, according to the clinical tolerance, in order to get an effective dose on the symptoms of ADHD to S4, not more than 1 mg/kg/d (capped at 60 mg/d). This gradual dose treatment will be resumed in the same manner in M3 at the beginning of the phase in open, allowing the respect of the average of the ADHD support (no), without loss of chance for the Group at 3 months, because it is customary to discontinue treatment during holiday periods).
Placebo Comparator: Matching Placebo	Other: Matching Placebo Methylphenidate delay shape, 10 and 30 mg and matching Placebo capsules. Treatment should be started at a dose of 10 mg per day or 20 mg/d (depending on the weight of patients), with increasing weekly, according to the clinical tolerance, in order to get an effective dose on the symptoms of ADHD to S4, not more than 1 mg/kg/d (capped at 60 mg/d). This gradual dose treatment will be resumed in the same manner in M3 at the beginning of the phase in open, allowing the respect of the average of the ADHD support (no), without loss of chance for the Group at 3 months, because it is customary to discontinue treatment during holiday periods).

Outcome Measures

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Primary Outcome Measures :

1. Number of days of use of cannabis [Time Frame: 12 weeks]

   Number of days of use of cannabis in the past 21 days measured in 12 weeks by the TimeLine Follow Back (TLFB 21)

Secondary Outcome Measures :

1. Number of days of use of cannabis [Time Frame: 4,8,12 weeks and 12 months]

   The average amount of daily consumption of cannabis within the past 21 days will be assessed from the TLFB 21-4, 8, 12 weeks and 12 months

2. Average daily consumption of cannabis in the last 21 days [Time Frame: 4,8,12 weeks and 12 months]

   will be evaluated from the TLFB 21. The TLFB 21 makes it possible to quantify the number of daily cannabis

3. ADHD Rating scale IV score [Time Frame: 4,8,12 weeks and 12 months]

   The scale evaluates the frequency of behavior, the level of behavioral discomfort and the developmental level.

4. advanced CAST score [Time Frame: one day, 12 weeks and one year]

   The CAST is a 6-item scale, each of which describes use behaviors or problems encountered in the context of cannabis use

5. the score of the Hooked on nicotine checklist (HONC) [Time Frame: one day, 4,8,12 weeks and 12 months]

   HONC is a self-administered questionnaire that assesses nicotine addiction.

6. the score of French version of the Tobacco Craving Questionnaire (FTCQ-12) [Time Frame: one day, 4,8,12 weeks and 12 months]

   Evaluation of tobacco craving from the four primary factors of tobacco craving: emotionality, craving in anticipation of withdrawal relief or negative mood; waiting, compulsion and anticipation

7. Psychiatric comorbidities [Time Frame: one day, 12 weeks and 12 months]
8. Consumption of other drugs [Time Frame: one day, 12 weeks and 12 months]
9. Score of Overall Clinical Improvement Scale (CGI-S) [Time Frame: one day, 4,8,12 weeks and 12 months]

   Measurement of symptom severity, response to treatment and efficacy of treatment in treatment studies of patients with mental disorders.

Eligibility Criteria
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Information from the National Library of Medicine

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:	12 Years to 25 Years (Child, Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Age ≥ 12 and ≤ 25 years;
- Patients from 25 to 120 kg
- ADHD diagnosed according to the criteria of the DSM - V
- ADHD-RS-IV ≥ 28 test score;
- Without medication by methylphenidate for at least 6 months;
- Lack of psychiatries co-morbidities associated with a contraindication to treatment with methylphenidate (confirmed by MINI or MINI Kid); absence of BPD (tracked by the self-administered questionnaire MSI - BPD).
- Cannabis dependence objectified by a positive qualitative urinary dosage and a score ≥ 7 to CAST questionnaire;
- Consent of parents (child/teenager < 18 years) or young age if ≥ 18 years - patients of childbearing age agreeing to use a contraceptive method during the duration of the test

Exclusion Criteria:

Patients placed in child welfare (ASE).

- Pregnant patients or nursing
- No affiliation to a scheme of social security (beneficiary or beneficiary)
- Contraindications to treatment with methylphenidate :known hypersensitivity to methylphenidate or any of the excipients, glaucoma, pheochromocytoma,treatment by non selective irreversible inhibitors of the mono-amine oxidase (MAOI) and also for at least 14 days after stopping treatment with an MAOI because of the risk of hypertensive thrust,Treatment by other sympathomimetic indirect or sympathomimetic (oral and/or nasal way) alpha,Hyperthyroidism or wrong,diagnosis or history of severe depression, anorexia nervosa or disorders anorexia, suicidal tendencies, mood disorders, psychotic symptoms, mania, schizophrenia, psychopathic personality disorder, or limit (borderline), occlusal,diagnosis or history (affective) bipolar disorder severe (for type 1) and episodic (and poorly controlled), pre-existing cardiovascular disorders including severe hypertension, heart failure, pad angina, congenital heart disease with hemodynamic impact; cardiomyopathy, myocardial infarction, arrhythmias and channelopathies (disorders caused by a dysfunction of ion channels) that can potentially be life-threatening, pre-existence of disorders, stroke, cerebral aneurysm, vascular abnormalities, including stroke or Vasculitis and major Patient protected by law.

Contacts and Locations

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Information from the National Library of Medicine

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): ***NCT03481959***

Contacts

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Sponsors and Collaborators

Assistance Publique - Hôpitaux de Paris

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Responsible Party: Assistance Publique - Hôpitaux de Paris

ClinicalTrials.gov Identifier: NCT03481959 History of Changes

Other Study ID Numbers: P140313
First Posted: March 29, 2018 Key Record Dates
Last Update Posted: March 29, 2018
Last Verified: May 2017

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

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

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

Keywords provided by Assistance Publique - Hôpitaux de Paris:
TDAH, Methylphenidate, cannabis

Additional relevant MeSH terms:

Disease
Attention Deficit Disorder with Hyperactivity
Hyperkinesis
Marijuana Abuse
Pathologic Processes
Attention Deficit and Disruptive Behavior Disorders
Neurodevelopmental Disorders
Mental Disorders
Dyskinesias
Neurologic Manifestations
Nervous System Diseases
Signs and Symptoms
Substance-Related Disorders
Chemically-Induced Disorders
Methylphenidate
Central Nervous System Stimulants
Physiological Effects of Drugs
Dopamine Uptake Inhibitors
Neurotransmitter Uptake Inhibitors
Membrane Transport Modulators
Molecular Mechanisms of Pharmacological Action
Dopamine Agents
Neurotransmitter Agents