

FAQ CBD-Cocaine

1. How long does this study last?

This double-blind randomized clinical trial lasts 92 days. It is divided into two phases, a first detoxification phase involving a 10-day hospitalization (without possibility to leave the ward) and a second weekly follow-up phase at an outpatient clinic for 12 weeks.

2. Where does the study take place?

The hospitalization takes place at the psychiatric ward located on the 11th floor of the Centre Hospitalier de l'Université de Montréal (CHUM). If you wish to, you will have the opportunity to visit the rooms and facilities during the eligibility visit to the study. The follow-up visits take place on the 5th floor of pavilion R of the CHUM research centre (CRCHUM) located on 900 St-Denis Street.

3. How does the hospitalization phase work?

You will be hospitalized for a period of 10 days on the 11th floor of the CHUM. You will have a single room and access to the common room. You will have room and board for this period. Members of the research team will come to see you every day and you will have the opportunity to participate in various activities and support groups. Throughout your stay, you will have access to all the regular clinical care for the treatment of your cocaine addiction.

4. What will happen during the study?

During the entire study, the participant will receive an experimental treatment for cocaine dependence. It will be either cannabidiol or placebo. The choice of treatment is determined randomly which means that it is impossible for the participant or the clinical staff to choose the treatment. During the hospitalization and the follow-up, the participant will fill out questionnaires, do different test batteries, give blood and urine for testing and engage in group psychotherapy. During the entire study duration, each participant benefits from a tight medical follow-up with a doctor and nurses in order to ensure his/her safety and well-being.

During hospitalization, one of the tests is the measure of cocaine craving, this intense desire to consume cocaine. The research team will develop with the participant collaboration different scenarios in order to trigger cocaine craving. This will be done in a safe environment.

5. Does the cannabidiol (CBD) has the same effect as cannabis?

No, cannabidiol (CBD) is one of the substances that is extracted from the cannabis plant but is not psychoactive.

6. Will there be any side effects?

The hospitalization goal is to induce withdrawal from cocaine and it is possible to suffer from fatigue, sleep disturbances, anxiety, craving or restlessness. Although no treatment is known to diminish these symptoms, all participants will benefit from a regular individual follow-up with a psychoeducation specialist, group therapy centred on toxicomania and relapse prevention as well as meetings with a social worker or a nurse.

Cannabidiol consumption is not without risk. For example, low blood pressure, dry mouth, body movement slowdown, dizziness and sedation have been reported. Furthermore, since cannabidiol can alter mental and physical capabilities, we strictly recommend not to drive neither use heavy machinery. Although cannabidiol is not carcinogenic, it can modify DNA (genetic material inside human cells). DNA damages have been associated with cancers in animals, although these results do not necessarily imply that cannabidiol cause genetic mutations in humans or increase the risk of cancer. Cannabidiol can also reduce immune system efficacy, which in turn increases the risk of infections. The risk for a person to be infected by the human immunodeficiency virus (HIV) or other infectious organisms can therefore increase with an acute risk of disease progression. Finally, cannabidiol can also have toxic effects on the testis and masculine fertility, which could alter conception capacities. Since cannabidiol affects foetus development, pregnant women or women desiring to conceive are not admissible to this study.

You could feel cocaine craving and anxiety during the experimental session measuring your desire to consume cocaine. In order to reduce to a minimum these undesirable effects, a relaxation session is offered and a specialist doctor in toxicomania will be on site to help if needed.

Blood tests can cause a malaise, pain at the puncture site, a bruise, an irritation or a rush. In rare case, infection and fainting can happen.

It is possible that some questions make you uncomfortable or that the length of the questionnaires generates fatigue or frustration.

7. Do I have to see a doctor at each follow-up visit?

No, it is not necessary to see a doctor at each visit, as long as your health is stable. You will have scheduled medical visits every 4 weeks.

8. Do I stop the treatment after the study ends?

Yes, you will need to stop taking the medication after the study ends since it is an experimental treatment that is not available in the market.

9. Will I be excluded from the study if I relapse?

No, you will be accompanied throughout the study by a team of health professionals, who can support you and encourage you through all stages of the process.

10. Will I know if I take CBD or the placebo?

No, since this is a double-blinded study, neither you nor the research staff will know if you had the placebo or the CBD. However, your study doctor may obtain this information in case of an emergency.