CTNPT 028: Cannabinoids in HIV-infected individuals on effective ART

hivnet.ubc.ca/clinical-trials/ctnpt-028-cannabinoids-hiv-infected-individuals-effective-art-safety-tolerability-effect-immune-function/

Hannah Branch

About the study (objectives)

Living with HIV is associated with higher rates of some chronic diseases and a relatively high level of inflammation within the body. Marijuana has anti-inflammatory properties that may be useful in counteracting this state of chronic inflammation. There is also evidence that it may have positive effects on immune function while reducing the harmful immune activation that contributes to inflammation. CNTPT 028, taking place at McGill University, is a small pilot study that will primary look at the feasibility, safety, and tolerability of cannabinoid oil in people living with HIV. Secondarily, it will test the effects of cannabinoid oils on immune function and inflammation.

About the disease/condition (background/context)

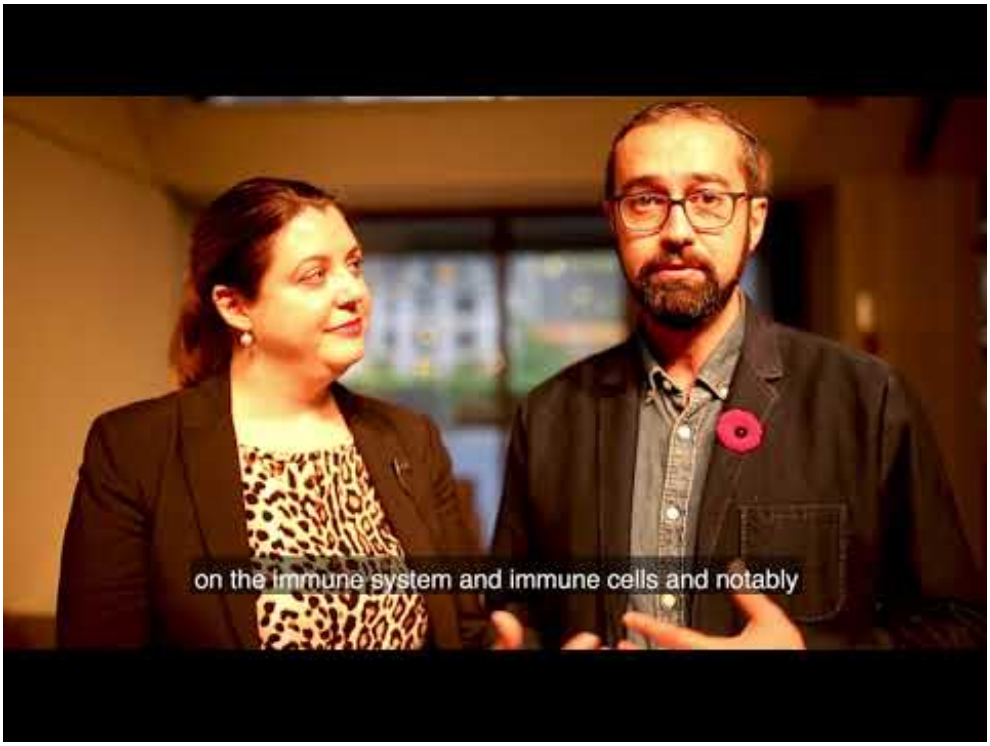
In the past, cannabis has been used to manage HIV-associated neuropathy and chronic pain and to stimulate appetite to combat AIDS wasting syndrome. More recently, laboratory and

animal studies suggest that cannabinoids have immunosuppressive effects—reducing T-cell activation, HIV production, and inflammatory markers—ultimately pointing towards the ability of these naturally occurring drugs to reduce immune activation.

Despite the potentially positive effects of marijuana for people living with HIV, only one study has tested its effect on immune function. No studies have tested its effect on inflammation or on the viral reservoir size (the amount of HIV that remains hidden in immune cells).

Study Approach (methodology)

Twenty-six participants will receive capsules for oral ingestion containing cannabinoid oils in set ratios of tetrahydrocannabinol (THC) and cannabidiol (CBD) for 12 weeks. Half of the participants will be randomized to the low dose arm (2.5 mg THC: 2.5 mg CBD) while the other half of participants will be randomized to the high dose arm (5 mg THC: 45 mg CBD). Participants in the low dose arm will take 1 capsule twice daily for 1 week and increase the number of capsules, as tolerated, to a maximum of 10 capsules taken throughout the day. The other participants will start by taking 1 high-dose capsule once daily for 1 week and increase the number of capsules, as tolerated, to a maximum of 5 capsules taken throughout the day. Toxicity and study completion will be the main outcomes however changes in quality of life, mood, immune function, and inflammation will also be measured using questionnaires and blood draws.



Watch Video At: https://youtu.be/R3HaMxpC_1c

Eligibility criteria

Required:

- Individuals will have suppressed viral load ≥3 years,
- no cannabinoid use for ≥1 month prior to enrolment as verified by negative baseline urine cannabinoid screen.

Not Allowed:

- pregnant women or women trying to become pregnant;
- active intravenous drug users;
- active substance dependence;
- prior history of hypersensitivity to marijuana or cannabis-containing products;
- active opportunistic infection or malignant condition;
- unintentional weight loss of 10% or more of body weight in the last 6 months;
- unstable angina or acute cardiac event in the past year;
- active psychiatric disorder or history of psychiatric depression (other than mild depression or anxiety);
- on antipsychotic medication;
- active liver disease; Hepatitis B or C infection
- holding a job which requires operation of heavy machinery or to undergo drug screening (ie, pilot or police officer);
- concurrent use within the past 8 weeks of anabolic hormones, prednisone, IL-2 or other agents known to alter immune system function.

Participating Sites

McGill University Health Centre
Chronic Viral Illness Service
Royal Victoria Hospital, Glen Site
1001 Décarie Blvd
Montreal, QC

Additional Information

If you would like more information on this clinical study, please contact the principal investigator.

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