

The Role of the Endocannabinoid System in Sweet Taste Intensity and Liking

Published: 03-07-2013

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The primary objective of this study is to assess if cannabinoids modulate sweet taste intensity and liking.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40528

Source

ToetsingOnline

Brief title

Sweed

Condition

- Other condition
- Appetite and general nutritional disorders

Synonym

Obesity, overweight

Health condition

Obesitas

Research involving

Human

Sponsors and support

Primary sponsor: Wageningen Universiteit

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Endocannabinoid system, Reward value, Sweet taste

Outcome measures

Primary outcome

The main study parameter is the sucrose intensity scaling (psychophysics) and liking (psychohedonics) of the milkshakes with the different sucrose concentrations.

Secondary outcome

The first secondary objective is to assess if cannabinoids influence the preferred sucrose concentration and the total amount of milkshake consumed in the preference task.

The second secondary objective is to see if the blood levels of endocannabinoids, leptin, ghrelin and insulin change during the course of the session and if there are differences between sessions.

The third secondary objective is to follow plasma levels of THC or CBD and their active metabolites.

The fourth secondary study objective is changes in liking of food products and in food choice in the food preference task. This also includes reaction time for the food choice questions.

The fifth and final secondary study objective is the genetic determination of the enzymes responsible for the metabolism of THC and CBD.

Study description

Background summary

The endocannabinoid (eCB) system has been found to be involved in food intake of sweet and palatable foods. Activation of the eCB system increases food intake and vice versa. The mechanism behind this effect is still unknown and the current study aims at clarifying why sweet food intake increases. It is hypothesized that activation of the eCB increases sweet taste intensity and that sweet taste is experienced as more pleasant.

Study objective

The primary objective of this study is to assess if cannabinoids modulate sweet taste intensity and liking.

Study design

Double-blind, placebo controlled human intervention study with a within-subjects design. To assess sweet taste intensity and liking, milkshakes with different levels of sucrose will be used.

Intervention

Each participant receives Δ 9-tetrahydrocannabinol (THC), cannabidiol (CBD) or placebo in three separate sessions that will be at least two weeks apart.

Study burden and risks

The study will consist of a 30 minute information session, a 90 minute practice session and three test sessions of approximately 150 minutes per session on separate days. During the last hour of each test session, participant are free to do what they want to do, as long as they stay in the room where the test session takes place. The study is non-therapeutic for participants. Participants will receive a low dosage of THC during one session and a dosage of the non-psychoactive substance CBD during another session. All participants have experience with cannabis and have never experienced an adverse reaction. The risk of an adverse reaction is therefore low. A medical doctor will be available and within a 5-minutes distance from the participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Male

Healthy

Incidental user of Cannabis

Exclusion criteria

Previously experienced an adverse reaction to cannabinoids (e.g. anxiety, paranoia, nausea, vomiting)

Having a family history of schizophrenia or other psychotic illness

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	30-04-2014
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO	
Date:	03-07-2013
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO	
Date:	23-08-2013
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO	
Date:	13-03-2014
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO	
Date:	20-03-2014
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)

Approved WMO
Date: 09-01-2015
Application type: Amendment
Review commission: METC Wageningen Universiteit (Wageningen)

Approved WMO
Date: 27-01-2015
Application type: Amendment
Review commission: METC Wageningen Universiteit (Wageningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2013-002555-14-NL
CCMO	NL44758.081.13