Effects of different forms of vaporized Cannabis sativa L. *Afina* in cannabis users

Published: 29-06-2020
Last updated: 09-04-2024

The primary objective is to evaluate the inhalation process and the overall satisfaction with the use of the Investigational Medicinal Products (IMPs). The secondary objectives are to determine the subjective effects after pulmonary administration...

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

Summary

ID

NL-OMON50058

Source
ToetsingOnline

Brief title
Effects of vaporized cannabis

Condition

- Other condition

Synonym
n.a.

Health condition

no health condition is addressed in the research, and healthy volunteers who are occasional cannabis users will be recruited

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Bedrocan International B.V.,industry

Intervention

Keyword: Cannabis, Cognition, Forms

Outcome measures

Primary outcome

The inhalation process and the overall satisfaction with the use of the IMPs

will be assessed by the means of Likert scales.

Secondary outcome

Subjective drug effects will be measured by a series of VAS/Bowdle

questionnaire/CADDS. The assessment of the quality of the IMPs by participants

will be measured by a series of Likert scales. Cognition will be assessed by a

computerized test battery. Memory, i.e. sensitivity to go along with suggested

self-incriminating statements will be assessed using an adjusted false

confession paradigm.

Study description

Background summary

In line with the current legal regulations, a medicinal cannabis product is considered standardized as long as the actual values of the active ingredients are within ±20% deviation from the declared values. These regulations are expected to change in the near future, by changing the limit to ±10% deviation. In order to comply with these stricter criteria, Bedrocan, the producer of medicinal cannabis in the Netherlands, needs to develop new forms of its cannabis products. There is a need to investigate which form of cannabis will result in an optimal experience for users (primary goal). Moreover, the study will also inquire the impact of these cannabis forms on cognitive and memory

functions during intoxication with Δ9-tetrahydrocannabinol (THC; secondary goal).

Study objective

The primary objective is to evaluate the inhalation process and the overall satisfaction with the use of the Investigational Medicinal Products (IMPs). The secondary objectives are to determine the subjective effects after pulmonary administration of the IMPs, to record the emergence of any potential adverse events, and the assessment of the quality of the IMPs by participants. In addition, we will assess how cannabis intoxication affects cognitive and memory function.

Study design

The study will employ a double-blind, randomized, placebo-controlled, crossover design. Occasional (N=25 incl. dropout) cannabis users will receive a single dose of vaporized cannabis (Bedrocan) containing 15 mg of THC, or placebo. There will be 4 separate sessions (with each session separated by a minimum of 7 days) in a randomised and counter-balanced order. During each of the 3 Bedrocan sessions, cannabis will be administered in a different form (granulate, powder, yellowcake).

Intervention

Participants will undergo 4 experimental conditions, in which they receive a fixed dose of Bedrocan cannabis in different forms (granulate, powder and yellowcake) or placebo. In each condition, the dose will contain 15 mg THC and <1.0% mg CBD.

Study burden and risks

The effects of THC occur very rapidly after inhalation and disappear within 2 to 3 hours. The given dose has been given to participants in previous studies with minor adverse events and is well tolerated in recreational cannabis users. Expected effects include mild relaxation, alteration of visual, auditory, and olfactory senses, fatigue, and appetite stimulation. Serious acute adverse effects of cannabis may include anxiety and panic attacks, vomiting, tachycardia and an increase in blood pressure; however, these are typically induced at much higher doses than what will be administered in this study. Placebo cannabis is not expected to cause any side effects, given that the concentrations of active cannabinoids are at negligible levels.

Contacts

Public
Universiteit Maastricht

Universiteitssingel 40
Maastricht 6229ER
NL
Scientific
Universiteit Maastricht

Universiteitssingel 40
Maastricht 6229ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Occasional cannabis users (>10 lifetime exposures and <= 2 times/week in the previous 3 months)
• Age between 18-50
• Good physical health as determined by medical examination and laboratory analysis
• Absence of any major medical, endocrine and neurological condition
• Normal weight, body mass index (weight/height2) between 18 and 30 kg/m2
• Written Informed Consent

Exclusion criteria

• History of drug abuse (other than the use of cannabis) or addiction (determined by the medical questionnaire, drug questionnaire and medical examination)
• Pregnancy or lactation (pregnancy test, if needed)
• Hypertension (diastolic > 90; systolic > 140)
• Current or history of psychiatric disorder (determined by the medical questionnaire and medical examination)
• Liver dysfunction
• Any serious prior adverse response to cannabis
• History of cardiac dysfunctions (e.g. arrhythmia, ischemic heart disease)

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-04-2021
Enrollment:	25
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Bedrocan (Cannabis Sativa L. 'Afina')
Generic name:	dronabinol/THC
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	29-06-2020
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-10-2020
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	EUCTR2020-002387-30-NL
CCMO	NL74382.068.20