Effects of vaporised cannabis, with and without CBD, on driving and cognition

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To examine and compare the effects of vaporized medicinal grade cannabis containing known concentrations and doses of the cannabinoids THC and CBD on on-road driving performance and cognitive function.

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

Summary

ID

NL-OMON47963

Source
ToetsingOnline

Brief title
Vaporised cannabis, driving and cognition

Condition

- Other condition

Synonym
niet van toepassing

Health condition

niet van toepassing

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: The University of Sidney

Intervention

Keyword: cannabidiol, cognition, delta-tetrahydrocannabinol, driving ability

Outcome measures

Primary outcome

Driving performance will be assessed using the on-road driving test. Outcome measures will include standard deviation of lateral position (SDLP), speed (MS) and standard deviation of speed (SDSP).

Secondary outcome

(1) Cognitive performance as assessed using the Divided Attention Task (DAT), Digit Symbol Substitution Task (DSST), Paced Auditory Serial Addition Task (PASAT), Tower of London (TOL) task;

(2) Subjective drug effects and confidence in driving ability as measured by a series of Visual Analog Scales (VAS); Cannabis effects on anxiety as measured by the State Trait Anxiety Inventory (STAI) and an emotional Stroop task,

(3) Plasma concentrations of THC, 11-OH-THC, THCCOOH and CBD.

Study description

Background summary

There is a growing need to better understand the impact of medicinal cannabis use on driving. Although prior research suggests that cannabis impairs driving performance in a dose-dependent manner, it is largely with respect to the effects of *9-tetrahydrocannabinol (THC) in recreational cannabis users. It is not clear to what extent these results can be generalised to medicinal cannabis

users. A recent pilot study suggests that there may be little difference between high and low CBD cannabis, despite anecdotal reports to the contrary, and that the effects of cannabis on driving may depend on the complexity of the task. This study will seek to validate these findings, primarily by using an on-road driving paradigm.

Study objective

To examine and compare the effects of vaporized medicinal grade cannabis containing known concentrations and doses of the cannabinoids THC and CBD on on-road driving performance and cognitive function.

Study design

Within-subjects, double-blind and placebo-controlled. Occasional cannabis users (N=24) will attend four test sessions, each one week apart, in which driving and cognitive function will be assessed following vaporisation of (1) THC/CBD containing cannabis, (2) THC only cannabis, (3) CBD only cannabis and (4) placebo cannabis. The order of these conditions will be counterbalanced across participants.

Intervention

Vaporized Bedrocan, Bedrolite and matched placebo cannabis (equivalent to 13.75 mg THC and CBD).

Study burden and risks

All participants will inhale cannabis and placebo vapor and will complete 2 on-road driving assessments in each session.

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

* Occasional cannabis users (>10 lifetime exposures and <2x/week in the last 12 months)
* Age between 20-50
* 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 20 and 28 kg/m2
* In possession of a valid driver license with at least 2 years driving experience (having driven > 3000 km/yr)
* 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
* Use of medications that may impact upon driving ability (e.g. mood stabilisers, sedatives)
* Any serious prior adverse response to cannabis
* History of cardiac dysfunctions (e.g. arrhythmia, ischemic heart disease)
* QT syndrome

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-05-2019
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO Date:	10-04-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-12-2019
Application type:	Amendment
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
CCMO	NL68411.068.19