

The effect of Cannabidiol (CBD) on paranoid cognitions in humans

Submission date 11/07/2013	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 16/08/2013	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 02/09/2020	Condition category Mental and Behavioural Disorders	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Background and study aims

The aim of this study is to find out about the effect of Cannabidiol (CBD) on brain function. CBD comes from the cannabis plant, but does not produce a 'high' as its effects in humans are almost undetectable except for mild sedation at high doses. The researchers want to learn more about the effect of CBD on the human mind in a simulated version of everyday life.

Who can participate?

People who are currently attending the OASIS clinic who are not currently taking any psychiatric medication, aged between 18 and 50, who are physically well, with no history of major illness.

What does the study involve?

The study involves two blocks of 5 days each. On day 1 of each block participants are given a capsule containing either CBD or placebo (dummy) in a random order. They are then given a box containing the remaining doses, and are asked to take a dose of CBD in the evenings for the next 3 days. On the 5th day of each block participants have the experimental session, where a small blood sample is taken to test how much CBD is in their body. They are then be asked to complete some questionnaires and finally complete the virtual-reality bus ride, followed by a simulated public-speaking task. Their heart rate is measured and small saliva samples are taken. The CBD week results are compared with the placebo week results.

What are the possible benefits and risks of participating?

Participants are paid £28 per day they are involved in the study, which is 10 days in total giving a maximum of £280. They are collected from home by taxi and dropped back home at the end of each day. Some people may experience mild sedation after taking CBD, so participants are asked not to drive, operate heavy machinery or engage in hazardous activities during the days they take any capsules. There are no documented effects of CBD on the heart or the nervous system aside from mild sedation, and no adverse effects have been recorded. It can very occasionally happen that some people experience a degree of nausea or disturbances in their vision after being in the virtual reality. Therefore if at any time they wish to stop, they can stop immediately.

Where is the study run from?

Institute of Psychiatry, King's College London (UK)

When is study starting and how long is it expected to run for?
July 2013 to August 2015

Who is funding the study?
The study is funded by an unrestricted grant from GW Pharma (UK)

Who is the main contact?
Dr Paul Morrison
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
3.2d30.5.13

Study information

Scientific Title
The effect of Cannabidiol (CBD) on paranoid cognitions in humans: a randomised controlled trial

Acronym
CBD VR2

Study objectives
CBD decreases perceived social threat and their endocrine sequelae.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Primary study design

Interventional

Study design

Randomised cross-over design

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Paranoid cognitions

Interventions

All participants will receive Cannabidiol (CBD) on one occasion, and placebo on the other. The order of administrations will be randomised and double-blinded. The drugs will be administered as oral capsules, 3 x 100 mg being taken twice a day (total dose per day is 600 mg).

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Cannabidiol

Primary outcome(s)

1. Autonomic arousal using pulse and respiratory rates and saliva swabs to measure cortisol
2. Paranoid thinking using the State-Social Paranoid Scale and the Cape-(state version)
3. Affective processing using the Beck Anxiety Inventory, the Bond and Lader Visual Analogue Scale and the Negative-Self-Statement-Scale

Key secondary outcome(s)

Cognitive functioning using the Letter-Number-Span to measure working memory, and the Hopkins-Verbal-Learning-Task-Revised

Completion date

22/08/2015

Eligibility**Key inclusion criteria**

1. Aged 18-50 years
2. English as first language
3. Patient at OASIS service

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

50 Years

Sex

All

Key exclusion criteria

1. Subjects who have been diagnosed with a major mental or physical illness (epilepsy, schizophrenia, bipolar disorder)
2. Subjects must not have had previous treatment with antipsychotic or mood stabilising drugs
3. Pregnancy
4. Drug/alcohol dependence

Date of first enrolment

22/07/2013

Date of final enrolment

01/01/2015

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Institute of Psychiatry

London

United Kingdom

SE5 8AF

Sponsor information**Organisation**

King's College London (UK)

ROR

<https://ror.org/0220mzb33>

Funder(s)

Funder type

Industry

Funder Name

GW Pharmaceuticals (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration