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

Submission date
11/07/2013

Recruitment status
No longer recruiting

Registration date
16/08/2013

Overall study status
Completed

Last Edited
02/09/2020

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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 mediation, 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)
National Research Ethics Service (NRES) Committee London, 30/05/2013

Study design
Randomised cross-over design

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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

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

Overall study start date
22/07/2013

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
20

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
England

United Kingdom

Study participating centre
Institute of Psychiatry
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
King's College London (UK)

Sponsor details
Institute of Psychiatry
16 DeCrespigny Park
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England
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Sponsor type
University/education

Website
http://www.kcl.ac.uk/iop/index.aspx

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Industry

Funder Name
GW Pharmaceuticals (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration