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Investigation of the potential beneficial effects of cannabidiol in the treatment of tardive dyskinesia

Submission date
15/04/2015

Recruitment status
No longer recruiting

Registration date
07/05/2015

Overall study status
Completed

Last Edited
13/12/2017

Condition category
Nervous System Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Antipsychotic medications ('antipsychotics') are used to treat people with symptoms of psychosis which usually occur in schizophrenia or bipolar depression. People with psychosis may hear voices or see things that aren't real. Antipsychotics affect the number of chemicals in the brain to help stabilise how people feel and reduce the symptoms of psychosis. Unfortunately, antipsychotics can have side effects such as stiffness and shakiness of the body. This is because they treat an area of the brain that is also involved in the control of muscle movement. Tardive dyskinesia (TD) is the name used to describe the involuntary sudden muscle movements of the face and/or body which can occur when people take antipsychotics. TD muscle movements and facial twitches can sometimes be painful and make sufferers feel very self-conscious. TD symptoms can disappear when a person stops their medication, but this isn't always the case. Also, some people are not able to stop their medication and must find ways to manage the symptoms of TD. There are some treatments that can be taken alongside antipsychotics to help control TD, including tranquiliser medicines or health supplements. Vitamin E is one such health supplement that has been shown to help TD symptoms. Cannabidiol (CBD), a compound found in cannabis, is being tested as a potential treatment for TD which can be taken alongside antipsychotics. CBD doesn't make people feel 'stoned', but it can control symptoms such as pain, muscle spasms and inflammation which are experienced in a variety of diseases and disorders. CBD usually comes in tablet form. The aim of this study is to compare how well CBD works on managing symptoms of TD compared with vitamin E when taken alongside antipsychotics.

Who can participate?
Adults taking antipsychotic medication for a psychotic disorder.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (intervention group) take CBD tablets twice a day for 6 weeks. Those in group 2 (control group) take vitamin E tablets daily for 6 weeks. Participants complete questionnaires and attend assessments at the start of the study, then 2 weeks, 4 weeks and 6 weeks during treatment, then at 12 weeks follow-up. Routine blood tests are carried out before the start of the trial.

What are the possible benefits and risks of participating?
The results of this study may benefit future patients if an improvement in the symptoms of TD is found. There are no significant adverse drug reactions to cannabidiol, but some mild and transient side effects include headache, dizziness and nausea.

Where is the study run from?
Federal Neuropsychiatric Hospital (Nigeria)

When is the study starting and how long is it expected to run for?
December 2015 to September 2019

Who is funding the study?
Federal Neuropsychiatric Hospital (Nigeria)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
IRB/14/271

Study information

Scientific Title
Investigation of the potential beneficial effects of cannabidiol in the management of oral-lingual-buccal dyskinesias using animal studies and a clinical trial

Study objectives
1. Hypothesis: there are significant differences and better outcomes for patients on cannabidiol in the management of oral-lingual-buccal dyskinesia.
1.1. Null hypothesis: there are no differences between cannabidiol and vitamin E in the

management of anti-psychotic induced oral-lingual-buccal dyskinesia.
2. Hypothesis: there is no difference or minimal difference in the side effect profile of cannabidiol and vitamin E when used in the management of antipsychotic induced oral-lingual-buccal dyskinesia.
2.1. Null hypothesis: patients on cannabidiol have more side effects than patients on vitamin E in the management of antipsychotic induced oral-lingual-buccal dyskinesia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee Nigerian Institute of Medical Research, 26/11/2014, ref: IRB/14/271

Primary study design
Interventional

Study design
Proof of concept, double blind placebo controlled study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Tardive dyskinesia

Interventions
1. Group 1 has high cannabidiol extract Nabidiolex® (CBD) (300mg) administered twice a day for six weeks as an adjunctive treatment alongside their usual antipsychotic medication. CBD will be administered orally in capsules.
2. Group 2 has vitamin E (400IU) administered daily for six weeks as an adjunctive treatment alongside their usual antipsychotic medication

Intervention Type
Mixed

Primary outcome(s)
Improvement in symptoms of tardive dyskinesia measured using the Abnormal Involuntary Movement Scale (AIMS). Assessments will be conducted at baseline, 2 weeks, 4 weeks, 6 weeks (post-treatment) and at 12 weeks follow-up.

Key secondary outcome(s)
1. Side effects of CBD will be periodically assessed with the Glasgow check list and reported at each assessment
2. Improvement in psychotic symptoms

Completion date
30/09/2019

Eligibility

Key inclusion criteria
1. Adults 18 years and older
2. Currently meets the ICD-10 diagnosis of a psychotic disorder, verified with the Mini International Neuropsychiatric Interview (MINI-PLUS) questionnaire.
3. Currently meets the clinical diagnosis of tardive dyskinesia confirmed with the Abnormal Involuntary Movement Scale (AIMS)
4. Patients should currently be receiving treatment for a psychotic disorder and should be on either the atypical or conventional antipsychotics
5. Patient gives informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. ICD-10 diagnosis of an organic mental illness, substance misuse disorder or a seizure disorder
2. Serious or chronic physical illness
3. Known severe drug allergies or hypersensitivity to CBD

Date of first enrolment
01/12/2015

Date of final enrolment
31/03/2019

Locations

Countries of recruitment
Nigeria

Study participating centre
Federal Neuropsychiatric Hospital
Yaba
Lagos
Nigeria
101212

Sponsor information

Organisation
Stellenbosch University

ROR
https://ror.org/05bk57929

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Federal Neuropsychiatric Hospital (Nigeria)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request