A RANDOMIZED DOUBLE-BLIND TRIAL, USING A SINGLE-BLIND RUN-IN TO ASSESS WITHDRAWAL SYMPTOMS AFTER PROLONGED TREATMENT WITH CANNABIDIOL (GWP42003-P)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Seizures (incl subtypes)
Study type	Interventional

Summary

ID

NL-OMON42668

Source
ToetsingOnline

Brief title
Cannabidiol (GWP42003-P) withdrawal trial

Condition

- Seizures (incl subtypes)

Synonym
epilepsy

Research involving
Human

Sponsors and support

Primary sponsor: PRA International EDS
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: cannabidiol, safety, withdrawal

Outcome measures

Primary outcome

To assess the occurrence of withdrawal symptoms induced by GWP42003-P using:

- cannabis withdrawal scale

- penn physician withdrawal checklist

Secondary outcome

The safety and tolerability of GWP42003-P will be assessed with respect to:

- adverse events

- vital signs

- ECG

- Clinical laboratory parameters

- physical examination

- C-SSRS

- NRS

- ESS

- C-SSRS

- HAM-D

Study description

Background summary

GWP42003-P (cannabidiol; CBD) is a new investigational compound that may eventually be used for the treatment of epilepsy. It is extracted from cannabis plants under highly controlled conditions to ensure the product is always the same. Within the human body there is a biological system named the endogenous cannabinoid system (ECS). CBD is absorbed and distributed very rapidly to tissues and a number of the therapeutic actions of CBD are thought to be produced via the body*s own ECS. In previous GW studies, CBD has not been associated with potential psychoactive effects that have been documented with recreational cannabis use.

GWP42003-P is not yet registered as a drug but has been given to humans in both clinical studies and as part of an approved product in combination with another drug for the treatment of spasticity in multiple sclerosis in a number of countries. GWP42003-P has been given to over 200 children and young adults at doses up to 25 mg/kg/day in the United States by GW Pharmaceuticals Ltd.

Study objective

The purpose of the study is to investigate to what extent GWP42003-P might lead to withdrawal effects after several weeks of dosing. Withdrawal effects are the signs and symptoms that can occur upon the abrupt discontinuation of some medications or recreational drugs.

It will also be investigated to what extent GWP42003-P has sedative effects and whether it influences your mood. In addition, the safety and tolerability of GWP42003-P will be investigated

Study design

The study will consist of 2 periods during which you will receive GWP42003-P or placebo twice daily for a total of 42 days. GWP42003-P and placebo will each be given as an oral solution. Each dose will be 7.5 mL.

Intervention

During the study GWP42003-P or placebo will be administered twice daily for a total of 42 days.

Study burden and risks

All drugs can cause adverse effects; the extent to which this occurs differs

between individuals.
The following side effects were experienced among a portion of the 213 patients (mainly children with severe epilepsy) who have taken GWP42003-P oral solution; however this was not within a formal clinical study (there was no placebo treatment). All were considered to be caused by the study compound. They have been categorized by the likelihood of them occurring, and listed in the order they have most commonly been reported.

Very common side effects which may affect more than one person in every 10 are: Feeling drunk, sleepy or abnormal, feeling tired, diarrhea and eating less than usual.

Common side effects which may affect more than one person in every 100 are (excluding the very common side effects above): Eating more than usual, weight gain, weight loss, convulsions (documented in children with pre-existing epilepsy), difficulty walking and amounts of medicines in the body were higher than usual (increased levels of other medicines).

Some patients have also developed rashes during treatment with GWP42003-P oral solution.

The following side effects have been seen in 107 patients who have previously taken other CBD medicines (either CBD botanical drug substance or purified CBD) within clinical studies. It should be noted that 87 of these patients took a formulation containing small amounts of other cannabinoids including tetrahydrocannabinol (THC) and so may have resulted in a higher incidence of side effects than with the study compound you will be using. They have been categorized by the likelihood of them occurring, and listed in the order they have most commonly been reported. The side effects in bold have been seen in 20 patients who have previously taken study medication of purified CBD, all being classed as common, with the exceptions of headache and diarrhea which were very common.

Very common side effects which may affect more than one person in every 10 are: Diarrhea, headache, feeling sick.

Common side effects which may affect more than one person in every 100 are (excluding the very common side effects above): Mouth problems (including, pain, discomfort, change in sense of taste or loss of sense of taste, dry mouth, reduction in or loss of sensation), feeling tired, indigestion, sickness, eating less than usual, feeling drunk or abnormal, feeling dizzy, neck pain, belching, urgency to pass motions, increased frequency in passing water, rashes, change in liver function blood tests or hematology blood tests, cold symptoms, abdominal pain, constipation, feeling depressed or confused, abnormal dreams, nose bleed, feeling weak or unwell, flushing, muscle spasms.

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

- healthy male/ female subjects
- 18-45 yrs, inclusive
- BMI: 18.0-28.0 kg/m2, inclusive

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. In case of participation in another drug study within 90 days before the start of this study or being a blood donor within 60 days from the start of the study. In case of donating more than 1.5 liters of blood (for men) / 1.0 liters of blood (for women) in the 10 months prior the start of this study.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-11-2015
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Cannabidiol
Generic name:	n/a

Ethics review

Approved WMO Date:	20-10-2015
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-11-2015
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	EUCTR2015-003692-30-NL
CCMO	NL55217.056.15