

The effects of inhaled delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD) on pain relief and subjective effects in fibromyalgia patients - A placebo controlled PKPD study

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1. Determination of the PK of THC, CBD after inhalation of cannabis products Bedrocan©, Bedrolite© and Bediol© 2. Determination of the analgesic effects of THC, CBD and the combination of THC and CBD after inhalation of cannabis products Bedrocan©,...

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

Summary

ID

NL-OMON42607

Source

ToetsingOnline

Brief title

Spirocan

Condition

- Other condition

Synonym

chronic pain, pain

Health condition

chronische pijn

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W, Bedrocan

Intervention

Keyword: cannabis (THC/CBD), fibromyalgia, pain, PKPD

Outcome measures

Primary outcome

Main end-points: PK data, spontaneous and experimental pain relief.

Secondary outcome

Secondary end-points: Blood pressure, cardiac output, temperature, mental state

(drug high, internal perception, external perception, depression, anxiety,

arousal, positive mood, alertness, contentment, calmness), psychomimetic side

effects.

Study description

Background summary

Various studies examined the effects of cannabinoids on pain relief in a multitude of pain syndromes (including neuropathic pain, fibromyalgia, spinal cord injury, diabetic neuropathy, general chronic pain, spasticity and neuropathic pain in multiple sclerosis, brachial plexus avulsion, rheumatoid arthritis, cancer pain, HIV neuropathy, post-traumatic neuropathy and Crohn's disease). Few studies addressed the effect of the highly purified components of medicinal cannabis, delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD).

In the current protocol we aim to study and model the pharmacokinetics and pharmacodynamics of inhaled medicinal cannabinoids: Bedrocan®, Bedrolite® and

Bediol© (Bedrocan, Veendam, The Netherlands) in fibromyalgia patients with chronic pain. We will study blood concentrations, pain relief (spontaneous and experimentally induced pain) as well as subjective effects.

Study objective

1. Determination of the PK of THC, CBD after inhalation of cannabis products Bedrocan©, Bedrolite© and Bediol©
2. Determination of the analgesic effects of THC, CBD and the combination of THC and CBD after inhalation of cannabis products Bedrocan©, Bedrolite© and Bediol©
3. Determination of the subjective effects of THC, CBD and the combination of THC and CBD after inhalation of cannabis products Bedrocan©, Bedrolite© and Bediol©
4. Determination of the hemodynamic and temperature effects of THC, CBD and the combination of THC and CBD after inhalation of cannabis products Bedrocan©, Bedrolite© and Bediol©

Study design

Dubble blind, randomized, placebo-controlled, crossover design

Intervention

1. inhalation of cannabis
2. questionnaires (HADS, Bond & Lader, Bowdle, POMS)
3. Blood sampling
4. pain testing
5. Cornea photo (Cornea Confocal Microscopy)

Study burden and risks

There are five distinct activities in this study, each with their own (limited) discomfort to the participants.

1. Inhalation of cannabis. In rare occasions cannabis can induces psychomimetic side effects, especially in subjects that are prone to such effects. Regarding psychotypical side effects, patients with a (family) history of psychotic disorders and bipolar disease will not be enrolled in the study. Regarding anxiety, some anxiety may occur but this is often self-limiting after reassurance. Additionally, (mild) nausea has been reported. We will assess the level of nausea and the decide whether additional treatment is required. Anti-emetics can be given via the intravenous access line
2. Intravenous line and arterial line. Apart from some possible bruising, no discomfort is expected from the placement of the intravenous and arterial lines.
3. Questionnaires. No discomfort is expected from the surveys.

4. Pain Testing. The pain testing is purposefully painful. No long-term effects are seen using the electrical and pressure pain tests.
5. Cornea Confocal Microscopy. The cornea will be anesthetized. Hence the test is painless. No discomfort is expected from this test.

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

Twenty pain patients diagnosed with fibromyalgia will be included if they have a pain score p(on a scale from 0 <= no pain to 10 <= most pain imaginable) for most of the day and meet the 2010 American College of Rheumatology diagnostic criteria.

Exclusion criteria

i) Unable to give written informed consent; (ii) medical disease such as pulmonary, renal, liver, cardiac, gastro-intestinal, vascular disease; (iii) allergy to study medication; (iv) use of strong opioids; (v) use of benzodiazepines; (vi) history of illicit drug use (incl. cannabis-related products) or alcohol abuse; (vii) (family) history of psychosis; (viii) epilepsy; (ix) raised intracranial pressure; (x) pregnancy and/or lactation; (xi) the presence of pain syndromes other than fibromyalgia.

Study design

Design

Study type: Interventional

Masking: Double blinded (masking used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated): 10-05-2016

Enrollment: 20

Type: Actual

Medical products/devices used

Product type: Medicine

Brand name: cannabis

Generic name: cannabis

Registration: Yes - NL intended use

Ethics review

Approved WMO

Date: 12-11-2015

Application type: First submission
Review commission: METC Leiden-Den Haag-Delft (Leiden)
metc-ldd@lumc.nl

Approved WMO
Date: 23-03-2016
Application type: First submission
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 23-09-2016
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 23-11-2016
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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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	EUCTR2015-003811-39-NL
CCMO	NL54902.058.15

Study results

Date completed:	11-12-2018
Actual enrolment:	20