Cannabis-opioid interaction in the treatment of fibromyalgia pain - an open label proof of concept study with randomization between treatment groups: cannabis, oxycodone or cannabis/oxycodon combination.;substudy: follow-up vragenlijst

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

Summary

ID

NL-OMON52397

Source
ToetsingOnline

Brief title
SPIRAL study

Condition

- Peripheral neuropathies

Synonym
pain

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Bedrocan, teler van de cannabis

Intervention

Keyword: fibromyalgia, pain, treatment

Outcome measures

Primary outcome

The main study outcome is the number of side effects observed during the course of treatment. To that end we will construct a composite side effects score. The score includes the following 10 symptoms dizziness (when getting up), sleepiness, insomnia, headache, nausea, vomiting, constipation, drug high, hallucinations, paranoia. The subjects will score all of these symptoms at the end of each day of treatment on paper. Each positive symptom will result in 1 point (max. score per day = 10) for the 42 days of treatment (= max. total score = 420).

Secondary outcome

The secondary outcome is pain relief. Each day the patient will give an indication of the efficacy of pain treatment.

Study description

Background summary

Rationale Currently, over 1.3 million individuals in the Netherlands (about 8% of the population) use an opioid for treatment of their often musculoskeletal (i.e. non-cancer) pain. Consequently, there is the imminent need for a replacement therapy or for an opioid-sparing therapy such that opioid load in the population is reduced significantly, and all opioid related morbidity is reduced (eg, opioid-related addiction, depression, hyperalgesia (reduced pain sensitivity), respiratory depression/death). One possible solution is to add a cannabis variant to the treatment of chronic pain in order to reduce and possibly even eliminate opioid therapy in chronic non-cancer pain. We previously successfully showed that two inhaled cannabis variants, 100 mg Bedrocan (22% THC or 220 mg per gram and less than 1% CBD) and 200 mg Bediol (6.3% THC or 63 mg per gram and 8% CBD or 80 mg per gram) produced a significant reduction of evoked pressure pain in patients with fibromyalgia compared to placebo cannabis. Here we propose a study to determine the effect of Bediol on top of opioid treatment on analgesia in patients with fibromyalgia pain. We will perform study with a three-way parallel design in patients with moderate to severe fibromyalgia pain. Patients will be randomized to receive Bediol treatment, Bediol + oxycodone treatment or just oxycodone treatment. All patients will be treated for 6 weeks and followed for another 6 weeks Objective The main objective is to assess whether Bediol (containing THC and CBD) co-treatment will reduce opioid side effects in chronic pain patients. A secondary objective will be that Bediol is superior to oxycodone in the relief of chronic fibromyalgia pain.

Study objective

The main objective is to assess whether Bediol (containing THC and CBD) co-treatment will reduce opioid side effects in chronic pain patients. A secondary objective will be that Bediol is superior to oxycodone in the relief of chronic fibromyalgia pain.

Study design

This is an open-label randomized controlled trial. Patients with fibromyalgia pain will be randomized 1:1:1 to receive daily oxycodone (Group 1), Bediol + oxycodone (Group 2), or Bediol. All patients will be treated at home.

Intervention

Treatment with oxycodone (Group 1), oxycodone and Bediol (Group 2) or Bediol (Groups 3) for 6 weeks.

Study burden and risks

At the doses applied in the current study and the close monitoring by the study team of the patients we foresee just limited concern for major issues. Both opioids and cannabis may have mental effects such as anxiety, drug high, and psychomimetic effects (issues with internal and external perception). We will closely monitor the patient and assess whether treatment should be modified in case of side effects.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Fibromyalgia patients with a pain score >= 5 (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 (Wolfe F, Clauw DJ, Fitzcharles MA, et al. The American College of Rheumatology preliminary diagnostic criteria for

fibromyalgia and measurement of symptom severity. Arthritis Care Res 2010; 62: 600-10). These criteria include (i) a widespread pain index (WPI) >= 7 (on a scale from 0 to 19); (ii) and a symptom severity (SyS) score >= 5 (on a scale from 0 to 12) or a WPI of 3-6 and a SyS score >= 9.

Exclusion criteria

(i) Unable to give written informed consent; (ii) presence of medical disease that may alter the pharmacokinetics of inhaled cannabinoids or oral oxycodone such as pulmonary or liver disease; (iii) allergy to study medication; (iv) prolonged use of strong opioids (> 3 months); (v) history of illicit drug abuse or alcohol abuse; (vi) (family) history of psychosis; (vii) pregnancy and/or lactation; (vii) the presence of pain syndromes other than fibromyalgia; (viii) age < 18 years.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-10-2019
Enrollment:	60
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Bediol

Generic name:	Bediol
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	OxyContin
Generic name:	oxycodon
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	20-05-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	17-07-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	04-03-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	08-04-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	05-08-2020

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

Approved WMO Date:	02-06-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	08-12-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	18-01-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	27-02-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	EUCTR2019-001861-33-NL
CCMO	NL69810.058.19