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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26860

Source
Nationaal Trial Register

Brief title
SPIRAL

Health condition

Fibromyalgia

Sponsors and support

Primary sponsor: Investigator-Initiated
Source(s) of monetary or material Support: Investigator-Initiated

Intervention

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 threeway 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) cotreatment 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

We hypothesize that the magnitude of side effects is reduced when Bediol is combined with oxycodone.

Study design

Patients will visit the laboratory eight times: screening visit and baseline visit; visits at 2 weeks, 4 weeks and 6 weeks of treatment; and three visits at follow-up (2 weeks, 4 weeks and 6 weeks).

Intervention

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.

Contacts

Public
LUMC
Monique van Velzen

0715262301
Scientific
LUMC
Monique van Velzen

0715262301

Eligibility criteria

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.
The WPI defines the number of body areas in which a patient experienced pain during the last

week; the SyS score indicates the level of other core symptoms of fibromyalgia such as fatigue, non-refreshing sleep and cognitive symptoms. Additionally, tender point examinations will be performed according to the 1990 American College of Rheumatology diagnostic criteria (Wolfe F, Smythe HA, Yunus MB, et al. The American College of Rheumatology 1990 criteria for the classification of fibromyalgia. Report of the Multicenter Criteria Committee. Arthritis Rheum 1990; 33: 160–172), however these results will not be considered for in- or exclusion. The presence of autonomic complaints such as diarrhea or obstipation, dizziness, dry mouth/eyes, etc. are no reason for exclusion in the chronic pain patient group, as these are symptoms consistent with the fibromyalgia syndrome (Niesters M, Dahan A: Fibromyalgia. In: Encyclopedia of the Neurological Sciences, 2nd edition, vol. 2. Edited by Aminoff MJ, Daroff RB. Oxford: Academic Press, 2014, pp. 288-292).

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 (> 3 months) use of strong opioids (oxycodone, fentanyl, buprenorphine, morphine) or tramadol (> 150 mg/day); (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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-07-2019
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	26-07-2019
Application type:	First submission

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
NTR-new	NL7902
Other	METC Leiden Den Haag Delft : P19.050

Study results