The analgesic efficacy of Δ9-THC (Namisol®) in patients with persistent postsurgical abdominal pain: a randomized, double-blinded, placebo-controlled, parallel design

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Primary Objective: - To investigate the analgesic efficacy of a stable dose Namisol® in patients suffering from persistent postsurgical abdominal pain. Secondary Objectives:- To investigate the effect of a stable dose Namisol® on central nervous...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Procedural related injuries and complications NEC
Study type	Interventional

Summary

ID

NL-OMON37384

Source
ToetsingOnline

Brief title
Δ9-THC in persistent postsurgical pain

Condition

- Procedural related injuries and complications NEC

Synonym
Abdominal postsurgical pain; adhesion pain

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: EU

Intervention

Keyword: Abdominal pain, Cannabis, Postsurgical pain, Tetrahydrocannabinol

Outcome measures

Primary outcome

• Pain intensity (diary)

o VAS average pain

Secondary outcome

• Pain intensity (diary)

o VAS minimal pain

o VAS maximal pain

• EEG

o ERPs to noxious electrical stimuli

o ERPs to auditory stimuli (oddball)

o FFT spontaneous EEG

• QST (visceral screenings protocol)

o Pressure pain thresholds

o Electric pain thresholds

o Electric wind-up response

o DNIC

• Questionnaires

o Izbicki

o PGIC

o PCS

o VASBond & Lader

o VASBowdle

o SF-36

o HADS

o PASS

• Pharmacodynamics

o Body Sway

• Functional

o Body weight

o Supplementary feeding

• Safety

o Laboratory

o ECG

o HF / BP

o Adverse events

• Pharmacokinetics

o THC, 11-OH-THC and THC-COOH concentrations

Study description

Background summary

Persistent postsurgical abdominal pain (PPAP) is a very difficult to treat pain. This pain can persist for months or even years and significantly

diminishes quality of life. The exact underlying cause for this pain persistence is still unclear, which makes its treatment still a challenge. The promising analgesic effects of Δ9-THC in previous research, plus the less variability in exposure to THC and its metabolites of Namisol® in comparison with previous Δ9-THC substances form the basis of the present research proposal.

Study objective

Primary Objective:
- To investigate the analgesic efficacy of a stable dose Namisol® in patients suffering from persistent postsurgical abdominal pain.

Secondary Objectives:
- To investigate the effect of a stable dose Namisol® on central nervous system processing (measured by EEG, QST, DNIC) in patients suffering from persistent postsurgical abdominal pain.
- To evaluate the effect of a stable dose Namisol® on anxiety and depression (HADS), general health (SF-36), pain catastrophizing (PCS), global impression of change (PGIC), pain related anxiety (PASS) in patients suffering from persistent postsurgical abdominal pain.
- To evaluate the effect of a stable dose Namisol® on safety and tolerability (adverse events) in patients suffering from persistent postsurgical abdominal pain.
- To evaluate the effect of a stable dose Namisol® on pharmacokinetics (PK) and pharmacodynamics (PD) in patients suffering from persistent postsurgical abdominal pain.
- To evaluate the effect of a stable dose Namisol® on body weight and the amount of supplementary food intake in patients suffering from persistent postsurgical abdominal pain.

Study design

A randomized, double-blind, placebo-controlled, parallel design to evaluate the analgesic properties of Namisol® during a 50-52 days add-on treatment.

Intervention

Namisol® with standardized Δ9-THC content or identical matching placebos will be administered orally to evaluate the analgesic properties of Namisol® during a 52 days add-on treatment to other analgesics. The study consists of two phases: a step-up phase (day 1-5: 3 mg TID; day 6-10: 5 mg TID), and a stable dose phase (day 11-52: 8 mg TID). The dosage may be tapered to at least 5 mg TID, when 8 mg is not tolerated.

Study burden and risks

The risks of participation include the possible side-effects of the study drug (i.e. tachycardia, feeling high, disturbance in attention, drowsiness, nausea) and findings of testing (i.e. positive test result for hepatitis B, hepatitis C or HIV). The patients participating will obtain no direct personal benefit. However, patients receiving active study treatment may experience pain relief during the investigation period. It is the hope that results conducted from the study will provide new insight to pain mechanisms, and future treatment options for CP patients. An alternative pain treatment is highly desirable in particularly this group of patients.

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

•Aged 18 years or older

•Postsurgical pain
•Standard analgesic treatment (paracetamiol/ NSAIDs) failed
•Pain duration exceeding 3 months, and average NRS>=3
•Stable doses intake of analgesics for the past 2 months
•The patient has been informed about the study, understood the information and signed the informed consent form

Exclusion criteria

•Regular cannabis use in past 3 years.
•Patient is diagnosed with irritated bowel syndrome (IBS), chronic pancreatitis or post cholecystectomy pain syndrome.
•Patient has an indication for a pain treatment other then medication
•Patient took cannabinoids on a regular basisin past 3 years
•Patient does not feel a pinprick test in the lower extremities
•Patient has a body mass index (BMI) above 33,0 kg/m2
•Patient has a significant medical disorder that may interfere with the study or may pose a risk for the patient
•Patient uses any kind of concomitant medication that may interfere with the study or may pose a risk for the patient
•Patient does not tolerate oral intake of medication or liquids, or is refrained from oral intake because of medical reasons
•Patient demonstrates clinical relevant deviations in the electrocardiogram (ECG)
•Patient has an actual moderate to severe renal impairment
•Patient has an actual moderate to severe hepatic impairment
•Patient has a presence or history of major psychiatric illness
•Patient has experienced an epileptic seizure in the past
•Patient demonstrates clinically significant laboratory abnormalities
•Patient demonstrates a positive urine drug screen for THC, cocaine, MDMA, and amphetamines
•Patient an active hepatitis B, hepatitis C or HIV infection
•Patient has a history of sensitivity / idiosyncrasy to THC
•Patient has a known or suspected lactose intolerance
•Female patient is pregnant or breastfeeding
•Patient intends to conceive a child during the course of the study
•Patient participates in another investigational drug study
•Patient has a clinical significant exacerbation in illness
•Patient is unwilling or unable to comply with the lifestyle guidelines

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-10-2012
Enrollment:	68
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	delta-9-tetrahydrocannabinol
Generic name:	Namisol

Ethics review

Approved WMO Date:	21-03-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-07-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-04-2014
Application type:	Amendment

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2012-000812-27-NL
ClinicalTrials.gov	NCTnognietbekend
CCMO	NL39962.091.12