Naltrexone as anti-craving medication in cannabis addicts.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28347

Source
Nationaal Trial Register

Health condition

cannabis addiction

Sponsors and support

Primary sponsor: Centrum Maliebaan

Bezoekadres:

Tolsteegsingel 2a

3582 AC Utrecht

Postadres:

Postbus 14116

3508 SE Utrecht

tel. algemeen: 030-234 00 34

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Source(s) of monetary or material Support: Centrum Maliebaan

Intervention

Outcome measures

Primary outcome

The initial assessment will entail the MATE-scale to establish the social and general functioning, a short depression questionnaire to rule out a depressive disorder, a thorough assessment of current cannabis use and the use of other addictive substances, validated questionnaires for subjective craving for cannabis (e.g. Desires for Drug Questionnaire, Obsessive Compulsive Drug Use Scale; Franken et al., 2002), a visual analogue scale for craving for cannabis (VAS; Franken and Muris, 2005), a VAS for craving for other addictive substances, blood pressure and pulse, basic blood lab of liver function and extra blood will be frozen for possible later research on genetic markers.

At two, four, six and eight weeks the assessment will ential an assessment of the use of the medication, of cannabis use, of the use of other addictive substances, of side effects, a VAS of craving for cannabis and a VAS of craving for other addictive substances.

At eight weeks the MATE-scale, blood pressure and pulse, and basic blood lab of liver function will also be measured.

Secondary outcome

If at the conclusion of the study there are clear distinct outcomes, we might use the extra blood for research on genetic markers.

Study description

Background summary

Naltrexone has been widely studied as an anti-craving medication in alcoholism since 1992. It works by blocking the opiate-receptors in the reward system. Over the years since its introduction Naltrexone has also been tried with other addictions. Its use in opiate addiction has been established. There have also been reports of its use in cocaine addiction and gambling addiction. The few studies in which Naltrexone has been studied in cannabis addiction have shown little, or no, favorable outcome.

The principal investigator in this study, Eugène Schouten, is psychiatrist in the addiction treatment facility (Centrum Maliebaan) in Amersfoort, The Netherlands. Since 2006 at this facility Naltrexone has been prescribed on an off-label basis for a variety of addictions. Its use in alcoholism and cocaine addiction is often, not always, confirmed by the patient and staff. Also many, not all, patients with cannabis addiction report a beneficial effect on craving and the abuse of cannabis. The wish to scientifically investigate the effect of Naltrexone in patients with cannabis addiction has led to this study.

Study objective

1. In patients with predominantly cannabis addiction, does Naltrexone significantly reduce craving for cannabis, significantly reduce use of cannabis, significantly increase general well-being on the MATE-scale, and have a sginificant effect on the use of other addictive substances?

2. Which are the side effects?

3. Do the side effects cause people to stop taking the medication (Naltrexone or placebo)?

4. Are there genetic markers which can predict which patients are more likely to respond well to Naltrexone?

Study design

0, then every week, through week 8.

Intervention

Naltrexone 50 mg/day or placebo will be administered for eight weeks.

Contacts

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Eligibility criteria

Inclusion criteria

1. Male of female, age 18-60 years;

2. Current DSM-IV diagnosis of cannabis abuse or dependence;

3. Able to provide written informed consent and to comply with all study procedures.

Exclusion criteria

1. Currently dependent on opiates;

2. Currently majorly dependent on another substance other than cannabis or nicotine;

3. History of depression that could be defined as even a single episode or recurrent episodes of depression, or depression necessitating hospitalization, or history of suicide attempt (see fotenote1);

4. Severe neurological or psychiatric disorders (e.g., psychosis, bipolar illness, dementia, or any diseases that require psychotropic medications);

5. Serious medical illnesses;

6. Known hypersensitivity or allergy to Naltrexone, or receiving chronic therapy with medication that could interact adversely with Naltrexone, within 30 days prior to randomization;

7. Known to go into surgery in the near future;

8. Received a drug with known potential for toxicity to a major organ system within the month prior to entering treatment;

9. Clinically significant abnormal laboratory values, as measured by the treatment centre;

10. Any disease of the gastrointestinal system, liver, or kidneys which could result in altered metabolism or excretion of Naltrexone.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2010
Enrollment:	60
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 35633
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2278
NTR-old	NTR2404
CCMO	NL25001.097.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35633

Study results

Summary results
N/A