

Naltrexone as anti-craving medication in cannabis addicts.

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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 significant effect on the...

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28347

Bron

NTR

Aandoening

cannabis addiction

Ondersteuning

Primaire sponsor: Centrum Maliebaan

Bezoekadres:

Tolsteegsingel 2a

3582 AC Utrecht

Postadres:

Postbus 14116

3508 SE Utrecht

tel. algemeen: 030-234 00 34

fax: 030-233 29 80

Overige ondersteuning: Centrum Maliebaan

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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 entail 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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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 significant 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?

Onderzoeksopzet

0, then every week, through week 8.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Heiligenbergerweg 34
E.A.M. Schouten
Amersfoort 3816 AK
The Netherlands
+31 (0)33 4220411

Wetenschappelijk

Heiligenbergerweg 34
E.A.M. Schouten
Amersfoort 3816 AK
The Netherlands
+31 (0)33 4220411

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-09-2010
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 35633
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A