

New pharmacotherapeutic treatment options for crack-cocaine dependent people in the Netherlands.

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Treatment retention of crack cocaine dependent patients increases when a pharmacological agent is added to standard outpatient psychosocial treatment.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20300

Bron

Nationaal Trial Register

Verkorte titel

CATCH-study

Aandoening

Cocaine dependence

Crack cocaine

RCT

Topiramate

Modafinil

Dexamphetamine SR

Psychosocial treatment

Ondersteuning

Primaire sponsor: Academic Medical Centre, Amsterdam, the Netherlands. Brijder Verslavingszorg (The Hague: 1 study site), BoumanGGZ/Antes (Rotterdam: 1 study site), and GGD Amsterdam (Amsterdam: 2 study sites).

Overige ondersteuning: ZonMw, the Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Data will be analysed following an intention-to-treat approach, consisting of all randomised patients that received TAU with at least one dose of the prescribed medication (experimental groups) or TAU only (control groups). The primary outcome measure is treatment retention, defined as the number of weeks attended following the start of treatment. In each sub-study, the treatment groups will be compared on length of treatment until dropping out or termination, using a Cox proportional hazards regression model. Compliance with the study medication can only be investigated in the experimental conditions.

Changes 04-04-2016: The primary outcome measure is defined as cocaine use, defined as the total number of days of crack-cocaine use during the 12 weeks study period (range: 0 – 84 days), and will be analyzed in a multivariate regression analysis, controlling for study group and treatment site interactions.

Toelichting onderzoek

Achtergrond van het onderzoek

Crack-cocaine has become one of the drugs of most concern in the Netherlands, being associated with a wide range of medical, psychiatric and social problems for the individual. Despite this status as one of the most problematic addictions, available treatment options for cocaine dependent users are limited at best. Psycho-social interventions for cocaine dependence generally show modest results, and there are no proven effective pharmacotherapies to date, despite the wide range of medications tested for this specific type of dependence, among others in the United States. The overall objective of this pharmacotherapeutic feasibility study is to investigate various potentially efficacious medications for their usefulness in the treatment of cocaine dependence, and – dependent upon the results – to yield one or more candidate medications for future investigation in a large-scale confirmatory controlled trial. The intervention study aims to evaluate, in crack dependent patients willing to participate in one of the new pharmacotherapies, the response to medically prescribed oral topiramate (Brijder Verslavingszorg, The Hague), oral modafinil (Jellinek/Mentrum, Amsterdam), and oral dexamphetamine SR (BoumanGGZ, Rotterdam), as an add-on to psychosocial treatment-as-usual (TAU), compared to TAU alone, in terms of acceptance, retention, compliance, potential efficacy, safety, and patient satisfaction.

Changes 04-04-2016:

1) The study will evaluate, in crack dependent patients with comorbid heroin dependence, the response to medically prescribed oral dexamphetamine SR (60 mg/day) as an add-on to

heroin assisted treatment, in terms of potential efficacy, acceptance, compliance, safety, and patient satisfaction.

Doel van het onderzoek

Treatment retention of crack cocaine dependent patients increases when a pharmacological agent is added to standard outpatient psychosocial treatment.

Onderzoeksopzet

1. Assessment at baseline, four, eight and twelve weeks;
2. Urinalysis at week 9-12.

Onderzoeksproduct en/of interventie

Psychosocial treatment (treatment as usual; TAU) compared with TAU added with experimental medication.

The intervention will study the effect of Topiramate, Dexamphetamine and Modafinil, as an add-on to a weekly outpatient psychosocial treatment as usual (TAU). The medications will be prescribed during the 12-week study period. Topiramate will be investigated in Brijder and will be titrated to a maximum oral dose of 200 mg/ day. Dexamphetamine will be studied in Bouman GGZ in sustained-release form in a daily, oral fixed dose of 60 mg. In Arkin, Modafinil will be prescribed in a fixed oral dose of 400 mg/ day.

Contactpersonen

Publiek

Parnassia Addiction Research Centre (PARC)
Monsterseweg 83
Mascha Nuijten
Den Haag 2553 RJ
The Netherlands
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Wetenschappelijk

Parnassia Addiction Research Centre (PARC)
Monsterseweg 83

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In the sub-studies of topiramate and modafinil, eligible patients must:

1. Be at least 18 years old;
2. Be cocaine dependent (DSM-IV) during at least the previous year;
3. Use cocaine on a regular basis (i.e., ≥ 8 days) in the previous month;
4. Administer their illicit cocaine primarily by means of basing ('crack');
5. Be able and willing to participate in outpatient psycho-social treatment and associated assessments;
6. Have provided written informed consent with regard to their assigned study treatment.

In the sub-study with dexamphetamine SR, the minimal duration of cocaine dependency will be five years instead of one year. In addition, these patients have to meet one extra inclusion criterion:

7. A history of earlier failed treatments aimed at reducing, or abstaining from, cocaine use ('treatment-refractory').

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients will be excluded in case of:

1. Severe medical (e.g., severe renal or kidney insufficiency/failure) or psychiatric problems (e.g. acute psychosis, current major depression, suicidal), which constitute a contra-indication for participation;

2. Cardiovascular problems (ECG);
3. Pregnancy or continued lactation;
4. Indication for treatment with naltrexone, disulfiram, or acamprosate;
5. Anticipated necessity of residential treatment (clinical judgement);
6. Insufficient command of the Dutch language;
7. Current participation in another addiction treatment trial.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-04-2010
Aantal proefpersonen:	216
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	21-10-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2459
NTR-old	NTR2576
Ander register	EudraCT // MEC : 2013-004024-1 // NL46415.018.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

1. Nuijten, M., Blanken, P., Van de Wetering, B., Nuijen, B., Van den Brink, W., & Hendriks, V. (2016). Sustained- release dexamphetamine in the treatment of chronic cocaine-dependent patients on heroin-assisted treatment: a randomised, double-blind, placebo-controlled, double-blind trial. The Lancet, in press. DOI:

[http://dx.doi.org/10.1016/S0140-6736\(16\)00205-1](http://dx.doi.org/10.1016/S0140-6736(16)00205-1).

2. Nuijten, M., Blanken, P., Van den Brink, W., & Hendriks, V. (2015). Modafinil in the treatment of crack-cocaine dependence in the Netherlands: Results of an open-label randomised controlled feasibility trial. Journal of Psychopharmacology, 29, 678-687.

3. Nuijten, M., Blanken, P., Van den Brink, W., & Hendriks, V. (2014). Treatment of crack-cocaine dependence with topiramate: A randomized controlled feasibility trial in The Netherlands. Drug and Alcohol Dependence, 138, 177-184.

4. Nuijten, M., Blanken, P., Van den Brink, W., & Hendriks, V. (2011). Cocaine Addiction Treatments to improve Control and reduce Harm (CATCH): New Pharmacological Treatment Options for Crack-Cocaine Dependence in the Netherlands. BMC Psychiatry, 11:135.