Innovative approaches for cocaine pharmacotherapy using fMRI: the case of varenicline.

Gepubliceerd: 11-08-2009 Laatst bijgewerkt: 18-08-2022

Varenicline reduces craving to cocaine and/or impulsivity in human cocaine users.

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22626

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

cocaine addiction

Ondersteuning

Primaire sponsor: AMC Amsterdam, The Netherlands
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Does varenicline reduce craving to cocaine and/or impulsivity in human cocaine users?

Toelichting onderzoek

Achtergrond van het onderzoek

A goal of the proposed study is to build knowledge for an evidence-based strategy to reduce relapse by cocaine addicts. To accomplish this, we propose to:

1. Investigate effects of prolonged treatment with varenicline (an alpha4-beta2 nicotinic receptor partial agonism) on the availability of dopamine D2 receptors in abstinent cocaine addicts;

2. Examine the acute and prolonged effects of varenicline on impulse control, motivational strength of drug cues, and brain activation patterns of cocaine-addicted patients compared to non-addicted controls (using fMRI);

3. Examine the extent to which these processes predict relapse.

Doel van het onderzoek

Varenicline reduces craving to cocaine and/or impulsivity in human cocaine users.

Onderzoeksopzet

All interventions are performed both before and after treatment, both for the placebo group and the varenicline-treated group.

Onderzoeksproduct en/of interventie

1. Study medication (varenicline 1mg twice daily);

2. fMRI scanning before and after treatment;

3. fMRI scanning after a single dose of varenicline;

4. SPECT scanning using the radioligand 123I-IBZM before and after treatment;

5. Neurocognitive tasks and questionnaires;

6. Blood and urine collections.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Male, age 18-60 years;

2. Current DSM-IV diagnosis of cocaine dependence, but recently detoxified and abstinent;

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 any substance other than cocaine or nicotine;

2. 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);

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

4. Serious medical illnesses;

5. Known hypersensitivity or allergy to varenicline, or receiving chronic therapy with medication that could interact adversely with one of the medications under study, within 30 days prior to randomization;

6. Drugs known to influence binding to DA2 receptors, including neuroleptics, and methylphenidate;

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

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

9. Any disease of the gastrointestinal system, liver, or kidneys which could result in altered metabolism or excretion of the study medication;

10. Hypersensitivity to Jodium.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	10-01-2009
Aantal proefpersonen:	30
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	11-08-2009
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	NL1839
NTR-old	NTR1949
Ander register	METC Academic Medical Center : MEC 08/197
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A