

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

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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

NTR

### 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.

## Doeleind 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

## **Publiek**

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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
Blinding:	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