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

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22626

Source
Nationaal Trial Register

Brief title
N/A

Health condition

cocaine addiction

Sponsors and support

Primary sponsor: AMC Amsterdam, The Netherlands
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

N/A

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	10-01-2009
Enrollment:	30
Type:	Unknown

Ethics review

Positive opinion

Date:	11-08-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL1839
NTR-old	NTR1949
Other	METC Academic Medical Center : MEC 08/197
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A