Innovative approaches for cocaine pharmacotheraphy: the case of rimonabant.

No registrations found.

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

Summary

ID

NL-OMON20293

Source
NTR

Brief title
Cocaine, Dopamine and Rimonabant (CoDoRi)

Health condition

addiction, cocaine, relapse, dopamine, DA D2 receptor, rimonabant, dopamine, neuro-imaging, SPECT, fMRI

Sponsors and support

Primary sponsor: Prof. dr. Wim Van den Brink
dr. Jan Booij
dr. Michelle Miller
drs. Cleo Crunelle

Source(s) of monetary or material Support: ZonMW / NIDA

Intervention

Outcome measures

Primary outcome

To assess the changes in DA D2 receptor availability in the striatum after 2 months of rimonabant treatment.
To assess whether rimonabant can decrease cocaine craving and/or impulsivity in human cocaine users.
To assess whether DA D2 receptor availability in the striatum can predict relapse to cocaine abuse in detoxified cocaine users.

Secondary outcome

N/A

Study description

Background summary

In today’s society, cocaine abuse and relapse remains a growing problem. Abstinent cocaine abusers have difficulties staying “clean”, and good treatment strategies for preventing relapse to cocaine abuse are lacking. Dopamine receptor availability in the striatum is linked closely to dependence and relapse disorders, and new imaging techniques allow us to investigate these effects.

Our goal is to build knowledge for an evidence-based strategy to reduce relapse in cocaine addicts. To accomplish this, we propose to:

a) investigate effects of prolonged treatment with rimonabant on the availability of DA D2 receptors in abstinent cocaine addicts using SPECT;

b) examine the acute and prolonged effects of Rimonabant on impulse control, motivational strength of drug cues, and brain activation patterns of cocaine-addicted patients compared to non-addicted controls (using fMRI and EEG); and,
c) examine the extent to which these processes predict relapse.

Study objective

Rimonabant increases the availability of dopamine D2 receptors in the brain's striatal area. This subsequently reduces cocaine craving and decreases relapse in human detoxified cocaine users.

Study design

SPECT will be performed at baseline, and after 2 months of rimonabant/placebo intake.

fMRI will be performed at baseline, after the first intake of rimonabant/placebo and after 2 months of medication intake.
Neuropsychological assessments will be assessed at consequent timepoints throughout the trial.

Intervention

Rimonabant or placebo will be administered for 2 months. [123I]IBZM SPECT will be performed at baseline and at the end of the experiment to assess the prolonged effects of rimonabant on DA D2 receptor availability in vivo. Additionally, fMRI and EEG will be performed at baseline, after the first tablet, and after two months, together with different neuropsychological assessments.

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 rimonabant, 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:	Non controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2008
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-05-2008
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	NL1268

Register	ID
NTR-old	NTR1314
Other	: MEC 07/301 #08.17.0109
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A