Why methylphenidate is not successful in cocaine-dependent ADHD patients: a SPECT study comparing DAT before and after methylphenidate treatment in ADHD patients with and without cocaine dependence.

No registrations found.

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

Summary

ID

NL-OMON26472

Source
Nationaal Trial Register

Brief title
N/A

Health condition

cocaine addiction, cocaine verslaving, ADHD, methylphenidate, methylfenidaat

Sponsors and support

Primary sponsor: Crunelle CL, Booij J, Van den Brink W
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

To compare the effects of a standard dose of methylphenidate (MPH) on Dopamine Transporter (DAT) occupancy in ADHD patients with and without cocaine dependence, in terms of:

1. Striatal occupancy of the DAT;

2. Symptoms of ADHD;

3. Neurocognitive functions associated with ADHD;

4. Drug use/craving (in the ADHD+SUD group);

5. Relations between DAT occupancy, ADHD symptoms, cognitive functions, and drug use/craving.

Secondary outcome

N/A

Study description

Background summary

The dopamine transporter (DAT) plays a fundamental role in both ADHD and substance use disorders (SUDs). DAT-selective medication, such as methylphenidate (MPH), have been shown to successfully block the DAT in ADHD patients and DAT occupancy has been associated with clinical effectiveness. In ADHD patients with SUD, however, these medications are not very effective, neither for treating ADHD nor SUD. This study is an attempt to seriously investigate one of the most plausible reasons for the difference in effectiveness of MPH in the treatment of adult ADHD patients with and without SUD. It is hypothesized that adult ADHD patients with SUD generally have higher baseline DAT availability in the basal ganglia (Jacobsen et al., 2000; Little et al., 1998, 1999; Malison et al., 1998), and that similar doses of MPH result in lower occupancy rates in adult ADHD patients with SUD compared to adult ADHD patients without SUD.

Study objective

To investigate the difference in effectiveness of methylphenidate (MPH) in the treatment of adult ADHD patients with and without comorbid cocaine dependence.

Study design

N/A

Intervention

1. MPH study medication (oral; Concerta 54 mg);

2. 2 SPECT scans using the selective radioligand [123I]FP-CIT;

3. MRI scan for coregistration;

4. Neuropsychological assessments, Questionaires;

5. Blood and urine analyses.

Contacts

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Eligibility criteria

Inclusion criteria

1. Male, age 18-60 years;

2. Current DSM-IV diagnosis of adult ADHD for all participants;

3. For the ADHD+SUD group: Current DSM-IV diagnosis of cocaine dependence, but abstinent from cocaine use for at least 1 week;

4. Able to provide written informed consent and to comply with all study procedures;

5. Negative urine analyses for MPH, amphetamines and cocaine.

Exclusion criteria

1. Currently dependent on any substance other than cocaine or nicotine;

2. Severe neurological or psychiatric disorders or diseases (e.g., psychosis, bipolar depression, Parkinson¡¯s disease, or dementia) that require psychotropic medications;

3. Serious medical illnesses that would make participation hazardous, such as cardiovascular disease or ECG abnormalities;

4. Known hypersensitivity or allergy to MPH;

5. Under therapy with drug known to influence binding to DATs, including antipsychotics, MPH, bupropion, and dexamphetamine within 30 days prior to randomization;

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

7. Clinically significant abnormal laboratory values (¡Ý3x normal) as measured by the Arkin Mental Health and Addiction treatment center;

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

9. Hypersensitivity to iodine;

10. Any contraindications to perform MR imaging (e.g., pacemaker, or any piece of metal in the body).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-01-2009
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	10-08-2009
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	NL1837
NTR-old	NTR1947
Other	METC Academic Medical Center : MEC 09/118
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A