Methylphenidate ADHD and SUD Study

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- short-term efficacy of MPH on ADHD symptomatology in adult male SUD patients with ADHD.- short-term influence of MPH on abstinence and drug use- short-term influence of MPH on cocaine craving - safety and adverse effects of MPH in this patient...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON30648

Source
ToetsingOnline

Brief title
MASS (Dutch: MAVO)

Condition

- Other condition
- Cognitive and attention disorders and disturbances

Synonym
Minimal Brain Dysfuntion; Addiction

Health condition

verslavingsproblematiek

Research involving
Human

Sponsors and support

Primary sponsor: Trimbos-instituut
Source(s) of monetary or material Support: Fonds Psychische Gezondheid.

Deelnemende verslavingszorginstellingen

Intervention

Keyword: ADHD, Effectiveness, Substance Use Disorder

Outcome measures

Primary outcome

- ADHD symptomatology

Secondary outcome

neuropsychological testing (stop task, contingency test, time reproduction test)

substance use

craving

adverse effects

Study description

Background summary

This project will contribute to the treatment-possibilities of adult ADHD patients with comorbid Substunce Use Disorders. ADHD is an invalidating, chronic and highly prevalent neurobiological disorder. The prevalence in children is 3-6%, in adults 1-3%. Most adult ADHD patients do have comorbid pscyhiatric disorders, of which Substance Use Disorders (SUD) is an important one.
ADHD is a highly prevalent comorbid disorder in adults with SUD; research in this area gives a range of this prevalence of 15-25% (Wilens, 2004)

Study objective

- short-term efficacy of MPH on ADHD symptomatology in adult male SUD patients with ADHD.
- short-term influence of MPH on abstinence and drug use
- short-term influence of MPH on cocaine craving
- safety and adverse effects of MPH in this patient group.

Study design

A-B-C-D design
randomised, double-blind, multiphasic study with placebo lead-in:
each participant receives in randomised sequence: 3 treatment phases (A-B-C) and 1 placebo phase (D)
duration: 9 weeks = placebo lead-in (1 week) + 4 phases (4 x 2 weeks)

evaluation: 10 times 1 baseline, 2 day 7 of placebo lead in, 3-10 day 7 and 14 of each phase

active treatment: methylphenidate (MPH) in 3 different dosage schedules
A = 7,5 mg 4 times a day (every 3 hours) B = 12,50 mg 4 times a day (every 3 hours)
C = 20 mg 4 times a day (every 3 hours)
D = Placebo

Intervention

See study design

Study burden and risks

Burden diagnoses (adhd, SUD, comorbid disorders: extra intensive procedure (partly comparable to care as usual) approximately3 hours.
Burden trial 9x 140 minutes.

Burden participation: later start of normal treatment procedures
Possible adverse effects- common to methylfenidate

Risks: Recent publications show that methylfenidat can safely be used in the treatment of ADHD patients with SUD.

Publications:
* Levin FR, Evans SM, Brooks DJ, Garawi F. Treatment of cocaine dependent treatment seekers with adult ADHD: double-blind comparison of methylphenidate and placebo. Drug Alcohol Depend. 2007 Feb 23;87(1):20-9.
* Levin FR, Evans SM, Brooks DJ, Kalbag AS, Garawi F, Nunes EV. Treatment of methadone-maintained patients with adult ADHD: double-blind comparison of methylphenidate, bupropion and placebo. Drug Alcohol Depend. 2006 Feb 1;81(2):137-48.
* Carpentier PJ, de Jong CA, Dijkstra BA, Verbrugge CA, Krabbe PF. A controlled trial of methylphenidate in adults with attention deficit/hyperactivity disorder and substance use disorders. Addiction. 2005 Dec;100(12):1868-74.

* Winhusen, T. et al 2006. Methylphenidate and cocaine: A placebo-controlled drug interaction study. Pharmacology, Biochemistry and Behavior 85 29-38

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

age: 18-65
ADHD according to DSM IV TR criteria
Alcohol and/or Cocaine dependence acoording to DSM IV TR criteria. In case of abuse this must be severe in such a way that the patient and his family suffer from severe negative consequenses of this abuse.

Exclusion criteria

severe psychiatric comorbidity (which need interventions first)
opiod abuse/dependence
severe physical problems

cardial problems

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-03-2008
Enrollment:	50
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	methylphenidate
Generic name:	methylphenidate
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	03-07-2007
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

Approved WMO

Date:	29-01-2008
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

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
EudraCT	EUCTR2007-003317-14-NL
CCMO	NL15806.097.07
Other	not available