

Clinical trial of long acting methylphenidate in amphetamine addicts with Attention Deficit Hyperactivity Disorder (ADHD)

Submission date 26/02/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 21/04/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/06/2010	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Acronym

Study objectives

ADHD is a pervasive childhood disorder highly prevalent in substance users. It is characterized by disabling problems of inattention, impulsivity and hyperactivity. ADHD is a known risk factor for substance use disorders (SUD) and has a negative effect on treatment outcome. Amphetamine is one of the most commonly used illicit drugs world wide causing severe physical and mental health problems for the individuals and their families and a huge financial cost for the communities.

Study hypothesis:

Does long acting methylphenidate (Concerta®) in combination with skills training reduce ADHD symptoms in amphetamine addicts with ADHD compared with placebo in combination with skills training?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional ethics committee in Stockholm, approved on 23/06/2004 (Dnr 04-396/1). Amendment approved on 17/02/2005 (Dnr 2005/200-32)

Study design

Prospective randomised double-blind placebo controlled single-centre trial.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Attention deficit hyperactivity disorder

Interventions

Participants are required to stay abstinent of any substance for minimum two weeks prior the inclusion.

Intervention group: Long acting methylphenidate (Concerta®) for 12 weeks, starting dose of 18 mg with 10-day titration up to max 72 mg + skills training

Control group: Placebo for 12 weeks + skills training

For subjects who do not tolerate the dose increase the dosage is adjusted and continued at the tolerated level.

Skills training: The main features in the treatment is assessing ADHD-symptoms and developing strategies to manage them such as exercises in mindfulness. Themes for the sessions are e.g., impulsivity, self-control, managing craving, risk situations for relapse.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

methylphenidate (Concerta®)

Primary outcome(s)

Reduction in self rated ADHD symptoms, assessed using the Conners' Adult ADHD Rating Scale (CAARS) at baseline and once a week for 12 weeks

Key secondary outcome(s)

1. Reduction in drug use: urine toxicology at baseline and weeks 4, 8 and 12
2. Observer rated ADHD symptoms, assessed using CAARS at baseline and once a week for 12 weeks
3. Psychiatric symptoms at baseline and weeks 4, 8 and 12
 - 3.1. Self rated craving assessed with Tiffany craving scale
 - 3.2. Change in symptoms of depression and anxiety assessed with Becks inventories
 - 3.3. Stroop test (test of selective attention)

Completion date

25/06/2007

Eligibility**Key inclusion criteria**

1. Male or female 18 to 65 years
2. Written consent
3. Amphetamine (amph) dependence according to the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV)
4. Used amh on minimum 10 days during the year before inclusion
5. ADHD according to DSM-IV
6. Living in Stockholm area

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Dependence (current or past) of opioids, cannabis or benzodiazepines
2. Have used opioids within 3 months before screening
3. Other serious psychiatric conditions such as suicidality or psychosis
4. Current treatment with benzodiazepines, antidepressants or neuroleptics
5. Heart condition or stroke or any other medical condition that is considered a risk
6. Pregnancy or breastfeeding
8. IQ <75

Date of first enrolment

14/02/2006

Date of final enrolment

25/06/2007

Locations

Countries of recruitment

Sweden

Study participating centre

Karolinska Institute

Stockholm

Sweden

171 76

Sponsor information

Organisation

Addiction Centre Stockholm (Beroendecentrum Stockholm) (Sweden)

ROR

<https://ror.org/04g380834>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Addiction Centre Stockholm (Beroendecentrum Stockholm) (Sweden)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2010		Yes	No