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

Submission date
26/02/2008

Registration date
21/04/2008

Last Edited
11/06/2010

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
MAHA

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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)

Overall study start date
14/02/2006

Completion date
25/06/2007

Eligibility

Key inclusion criteria
1. Male or female 18 to 65 years
2. Written consent
3. Amphetemine (amph) dependence according to the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV)

4. Used apmh on minimum 10 days during the year before inclusion
5. ADHD according to DSM-IV
6. Living in Stockholm area

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24

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)

Sponsor details
Box 17914
Stockholm
Sweden
118 95

Sponsor type
Hospital/treatment centre

Website
http://www.beroendecentrum.com

ROR
https://ror.org/04g380834

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Addiction Centre Stockholm (Beroendecentrum Stockholm) (Sweden)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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