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Clinical trial of sustained release methylphenidate for Attention Deficit Hyperactivity Disorder (ADHD) in adult criminal offenders with amphetamine addiction

Submission date
03/09/2007

Recruitment status
No longer recruiting

Registration date
26/10/2007

Overall study status
Completed

Last Edited
12/06/2015

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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
MKJF001

Study information

Scientific Title
Clinical trial of sustained release methylphenidate for Attention Deficit Hyperactivity Disorder (ADHD) in adult criminal offenders with amphetamine addiction

Study objectives
Attention Deficit Hyperactivity Disorder (ADHD) is a common childhood condition that in many cases persists into adulthood. Approximately 1 - 2 % of the adult population is affected. ADHD is characterised by problems with attention, hyperactivity and impulsivity and leads to disabling difficulties in many areas of life. Additional psychiatric problems are common, abuse of drugs and alcohol being one of the most frequent. An estimated 30% of the individuals with substance use have ADHD. Amphetamine use is a major problem in Sweden and internationally. Many of amphetamine dependent individuals are also involved in criminal activity and relapse rate in criminality is very high for the abuse population. So far there is no evidence-based pharmacotherapy for amphetamine dependency. Few studies have addressed the question of treating ADHD with stimulants in substance dependent population.

Hypothesis:
Does sustained release methylphenidate combined with psychosocial treatment (relapse prevention) in amphetamine dependent individuals with ADHD significantly lower the risk for relapse to substance abuse compared with placebo and psychosocial treatment (relapse prevention)?

On 18/11/2010 the overall trial end date was changed from 30/06/2009 to 30/09/2011.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Regional Ethics Committee in Stockholm on the 12/06/2006 (ref: 2006/585-31/2). Amendment approved on the 27/09/2006 (ref: 2006/1103-32).

Study design
Single-centre double-blind randomised placebo-controlled with parallel groups

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Attention Deficit Hyperactivity Disorder (ADHD)

Interventions
Inmates who volunteer for the study are screened with the adult ADHD Self-Report Scale (ASRS) and Wender Utah Rating Scale (WURS) and the Structured Clinical Interview for DSM-IV (SCID-I) by a psychologist and a physician. Individuals who meet the study criteria undergo a neuropsychological assessment and baseline measurements are completed. Subjects also undergo a physical examination, checking their blood pressure; they also leave a urine specimen and a blood sample to test liver function and hepatitis. 14 days before their release they are included in the study given that they meet all the parameters required.

Subject are randomised into sustained release Methylphenidate (MPH) group or placebo group. The randomisation is handled by an independent pharmacist. Starting dose is 18 mg with 19-day titration to maximum dose of 180 mg. For patients who do not tolerate dose increase the dosage will be adjusted and continued at the tolerated level.

After their release subjects attend an out patient clinic twice a week and are seen by a research nurse. At each visit subjects collect the medication needed until next visit. They are also required to produce a urine specimen and fill in forms or take tests required for that visit. Once a week all subjects receive cognitive behaviour therapy (Relapse Prevention [RP]). RP starts at week 1 while subjects are still in prison and continues for 12 weeks. At weeks 13 - 24 subjects meet a psychologist/coach every fortnight for help in practical matters.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Methylphenidate

Primary outcome measure
Percentage of urine samples with no trace of drugs of abuse (amphetamines, opioids, benzodiazepines, delta-9-Tetrahydrocannabinol (THC), cocaine, dextropropoxifen, buprenorphine), analysed at week 12 and 24.

Secondary outcome measures
The following will be analysed at week 12 and 24:
1. Relapse to crime (readmission to prison or other legal action for criminal offence, self-reported criminality)
2. Self-reported reduction in ADHD-symptoms, assessed using the Conners' Adult ADHD Rating Scales (CAARS)
3. Reduction in psychiatric symptoms, assessed using Outcome Questionaire 45
4. Plasma concentration of methylphenidate
5. Clinician reported reduction in ADHD-symptoms (Clinical Global Impressions [CGI] scale)
6. Self-reported drug-craving measured on a Visual Analogue Scale (VAS)

7. Reduction of problems in attention assessed by Connors' Continuous Performance Test (CPT)
8. Self-reported drug use, assessed using the Addiction Severity Index (ASI) and time-line follow-back
9. Interpersonal Problems (IIP)

Overall study start date
12/04/2007

Completion date
30/09/2011

Eligibility

Key inclusion criteria
1. Male prison inmates
2. 18 to 65 years of age
3. Those who meet the Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM-IV) criteria for amphetamine addiction and for ADHD
4. Those who, after release from prison, have an address and phone number in Stockholm area where they can be reached

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
54

Key exclusion criteria
1. Opioid, alcohol, cannabis or benzodiazepine addiction
2. Other serious psychiatric conditions apart from substance abuse/addiction (i.e. dementia, severe depression with suicidal ideation, acute psychotic symptoms, chronic schizophrenic syndrome)
3. Ongoing medication with benzodiazepines or neuroleptics
4. Acute symptoms of withdrawal regardless of substance
5. Known heart condition
6. History of stroke
7. Other severe medical condition (cancer, hypertension, glaucoma, advanced arteriosclerosis, liver cirrhosis or any medical condition that could mean a risk for the patient)
8. Known hypersensitivity to methylphenidate

Date of first enrolment

12/04/2007

Date of final enrolment
17/05/2011

Locations

Countries of recruitment
Sweden

Study participating centre
Karolinska Institute
Stockholm
Sweden
17176

Sponsor information

Organisation
Addiction Centre Stockholm (Beroendecentrum Stockholm) (Sweden)

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Sponsor type
Hospital/treatment centre

Website
http://www.beroendecentrum.com/

ROR
https://ror.org/04g380834

Funder(s)

Funder type
Not defined

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

Funder Name
National Psychiatric Services Coordination Taskgroup (Nationell Psykiatri Samordning) (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