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Naltrexone for the treatment of amphetamine dependence: a randomised placebo controlled trial

Submission date	Recruitment status	[_] Prospectively registered
15/11/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/11/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/05/2019	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Study information

Scientific Title
Naltrexone for the treatment of amphetamine dependence: a randomised placebo controlled trial

Study objectives
Amphetamine abuse and dependence represents a major public health problem with growing psychiatric, social and economic consequences. The total number of amphetamine abusers world-wide is estimated to 34 million, a figure larger than the combined number of cocaine and heroin abusers. In Sweden, amphetamine is the most commonly abused substance after cannabis and alcohol. To date, the development of an efficacious pharmacotherapy has remained elusive, although the neurobiological effects of amphetamine have been investigated extensively.

Hypothesis:
To investigate the effect of chronic treatment of naltrexone on amphetamine dependence. With the specific aim of assessing the efficacy of naltrexone in comparison to placebo in increasing weeks of abstinence in amphetamine dependent patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. The Regional Ethical Review Board in Stockholm on the 6th May 2002 (ref: 03-132)
2. The Swedish Medical Products Agency on the 20th August 2002 (ref: 151:2002/26412)

The trial was conducted in accordance with Good Clinical Practice (ICHGCP, 1996) and the Declaration of Helsinki.

Study design
This was a randomised double-blind placebo-controlled 12 week study.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Amphetamine abuse and dependence

Interventions
This was a randomised, double blind, single-site placebo-controlled trial of Naltrexone (NTX) for amphetamine dependence. Post the lead-in period, 80 patients were randomised to either placebo or NTX treatment for 12 weeks. Patients were asked to attend the clinic twice weekly. On the first weekly visit they met with a research nurse, left supervised urine samples, collected the weekly medication (50 mg naltrexone or an identical placebo in blisters of 7 each), dispensed by the research nurse and filled out questionnaires. On the second weekly visit they received relapse prevention therapy from a licensed psychologist and in addition left supervised urine samples. All urine samples were screened for amphetamine, benzodiazepines, cannabis, cocaine (benzoylecgonine), dextropropoxyphen and opiates. Weekly assessments also included craving measures, self reports of drug use and monitoring of adverse events.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome(s)
The primary outcome measure of the study was abstinence from amphetamine use, as measured by negative amphetamine urine samples during 12 weeks of treatment (maximum of 24 samples). All missing urine samples were imputed as positive in the analysis. The primary analysis was carried out according to the Intention-To-Treat (ITT) approach.

Key secondary outcome(s))
Secondary outcomes measures included the following:
1. Self reported use of amphetamine (as measured by Timeline Follow Back)
2. Self reported use of alcohol and other drugs of abuse (as measured by Timeline Follow Back)
3. Compliance to treatment, defined as:
3.1. 16/24 urine samples
3.2. Medication compliance, detected by the presence of 6-β-naltrexol in the urine
3.3. Pill counts
4. Craving for amphetamine, measured by the amphetamine craving scale
5. Adverse events, monitored by the study physician and weekly self-report by patient

All secondary outcome measures were evaluated on a weekly basis.

Completion date
23/06/2005

Eligibility

Key inclusion criteria
1. Adult male or female between 18 to 65 years
2. Written, informed consent to participate
3. Address and telephone in the Stockholm metropolitan area where the participant can be reached
4. Amphetamine dependence according to Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) criteria
5. Having used amphetamine on a minimum of 12 occasions during the 12 weeks prior to screening
6. Two consecutive urine tests with no traces of amphetamine following screening

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
80

Key exclusion criteria
1. Opiate abuse or dependence
2. Use of any opiate preparation (legal or illicit) during 30 days prior to screening
3. Presence of opiates in urine at screening
4. Other mental disorders than substance abuse/dependence considered to be severe and requiring treatment (dementia, severe depression with suicidal ideation, acute psychotic symptoms, schizophrenia - concurrent pharmacological treatment for depression, and mild psychotic symptoms such as paranoid ideation or other forms of milder delusions for which the patient has some degree of insight do not constitute exclusion criteria)
5. Ongoing treatment with benzodiazepines
6. Acute withdrawal symptoms at screening, irrespective of cause
7. Serious somatic disorder (e.g., cancer, moderate to severe hypertension, advanced atherosclerosis, liver cirrhosis, or other disorders considered to be a risk)
8. Known hypersensitivity to naltrexone

Date of first enrolment
10/01/2003

Date of final enrolment
23/06/2005

Locations

Countries of recruitment
Sweden

Study participating centre
Department of Clinical Neuroscience
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Sponsor information

Organisation
Addiction Centre Stockholm (Beroendecentrum Stockholm) (Sweden)

ROR
https://ror.org/04g380834

Funder(s)

Funder type
Government

Funder Name
Swedish Science Council (Sweden)

Funder Name
The Swedish National Drug Policy Coordinator (Sweden)

Funder Name
The Stockholm County Council (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	01/11/2008	31/05/2019	Yes	No