

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

Submission date
15/11/2007

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
16/11/2007

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
31/05/2019

Condition category
Mental and Behavioural Disorders

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

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

Stockholm

Sweden

17176

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