

# Naltrexone depot implant in the treatment of co-morbid amphetamine and opioid dependence

<b>Submission date</b> 25/10/2007	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/10/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/08/2019	<b>Condition category</b> Mental and Behavioural Disorders	<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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers**  
84/24.9.2007

## Study information

**Scientific Title**

Naltrexone depot implant in the treatment of co-morbid amphetamine and opioid dependence: a double-blind, randomised, placebo-controlled trial

**Study objectives**

The purpose of this study is to compare the efficacy of naltrexone depot implant (Prodotoxone) with placebo in reducing amphetamine and opioid use among patients having amphetamine (or methamphetamine) and opioid dependence.

As of 22/12/2009 this record has been updated in response to changes in the protocol. All updates can be found under the relevant field with the above update date. At this time, the anticipated start and end dates of this trial were updated; the initial trial dates were:

Initial anticipated start date: 10/11/2007

Initial anticipated end date: 31/12/2009

At this time, the sponsor was also updated; the initial sponsor of this trial was the National Research and Development Centre for Welfare and Health (STAKES) (Finland).

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics approval received from the Independent Ethical Committee, St. Petersburg State Pavlov Medical University on the 24th September 2007 (ref: 84).

**Study design**

A parallel double-blind, randomised, placebo-controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Treatment

**Participant information sheet****Health condition(s) or problem(s) studied**

Amphetamine and opioid dependence (DSM-IV)

**Interventions**

The naltrexone arm will receive Naltrexone depot implant (Prodotoxone) (containing 1000 mg of naltrexone), and the placebo arm will receive an identical-looking placebo implant. The patient receive only one implant in the beginning of the study and the follow-up is 10 weeks for both arms.

**Intervention Type**

Drug

**Phase**

Not Applicable

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

Naltrexone (Prodetozone)

**Primary outcome measure**

Current information as of 22/12/2009:

1. Retention in the study
2. The proportion of urine samples, which are free of both amphetamine and opioids ("totally clean") during the follow-up. Missing samples are considered as amphetamine and opioid positive samples.
3. Improvement in Clinical Global Impression (CGI) during the follow-up

Initial information at time of registration:

1. Amphetamine concentration in the urine samples and proportion of amphetamine-negative urine samples in each arm, obtained each week
2. Proportion of opioid-dependent patients (assessed with naloxone challenge test) in each arm, measured at at week 10

**Secondary outcome measures**

Current information as of 22/12/2009:

1. The proportion of amphetamine free urine samples during the follow-up. Missing samples are considered as amphetamine positive samples.
2. The proportion of opioid free urine samples during the follow-up. Missing samples are considered as opioid positive samples.
3. Global Assessment of Functioning (GAF)
4. Number of days amphetamine used during follow-up
5. Adverse events

Initial information at time of registration:

Proportion of benzodiazepine-negative and cannabinoid-negative urine samples, obtained each week.

**Overall study start date**

01/03/2008

**Completion date**

28/02/2011

## **Eligibility**

**Key inclusion criteria**

1. Primary diagnosis of current Amphetamine and Opioid Dependence (Diagnostic and Statistical Manual of Mental Disorders, fourth edition [DSM-IV]), present for at least one year
2. Age between 18 and 50 years
3. Education as high school graduate or above
4. Negative urine toxicology and alcohol breath tests
5. Not currently on psychotropic medication

6. At least one relative willing to participate in treatment, monitor administration of medications, assist in follow-up, and provide outcome data
7. Stable address within St. Petersburg or nearest districts of Leningrad Region
8. Home telephone number at which the patient can be reached
9. Negative pregnancy test and use adequate contraception if of childbearing age
10. Willingness and ability to give informed consent and otherwise participate

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

100 patients

**Total final enrolment**

100

**Key exclusion criteria**

1. Clinically significant cognitive impairment, schizophrenia, paranoid disorder, bipolar disorder, or seizure disorder
2. Advanced neurological, cardiovascular, renal, or hepatic disease
3. Active tuberculosis or current febrile illness
4. Acquired Immune Deficiency Syndrome (AIDS)-defining illness
5. Significant laboratory abnormality such as severe anaemia, unstable diabetes, or liver function tests greater than 3 x above normal
6. Pregnancy
7. Pending legal charges with potential impending incarceration
8. Concurrent participation in another treatment study
9. Concurrent treatment in another substance abuse program

**Date of first enrolment**

01/03/2008

**Date of final enrolment**

28/02/2011

**Locations****Countries of recruitment**

Finland

Russian Federation

**Study participating centre**  
**Niuvanniemi Hospital**  
Kuopio  
Finland  
FI-70240

## Sponsor information

### Organisation

National Institute for Health and Welfare (THL) (Finland)

### Sponsor details

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### Sponsor type

Research organisation

### Website

<http://www.thl.fi>

### ROR

<https://ror.org/03tf0c761>

## Funder(s)

### Funder type

Government

### Funder Name

Current information as of 22/12/2009:

### Funder Name

Ministry of Health and Social Affairs (Finland) - National Institute for Health and Welfare (THL)  
and EVO-subsidies from Niuvanniemi Hospital

## Funder Name

Initial information at time of registration:

## Funder Name

Ministry of Health and Social Affairs (Finland) - Government of Finland, from National Research and Development Centre for Welfare and Health (STAKES) and EVO-subsidies from Niuvanniemi Hospital

## 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?
<a href="#">Results article</a>	results	01/05/2012	21/08/2019	Yes	No