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

Submission date 25/10/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [X] Results [ ] Individual participant data
Registration date 30/10/2007	**Overall study status** Completed	
Last Edited 21/08/2019	**Condition category** Mental and Behavioural Disorders	

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 (Prodetoxone) 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 (Prodetoxone)

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
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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?
Results article	results	01/05/2012	21/08/2019	Yes	No