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Methylphenidate in the treatment of amphetamine dependence: a double-blind randomised, placebo-controlled trial

Submission date
07/09/2005

Recruitment status
No longer recruiting

Registration date
13/09/2005

Overall study status
Completed

Last Edited
26/10/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
64/2003

Study information

Scientific Title
Methylphenidate in the treatment of amphetamine dependence: a double-blind randomised, placebo-controlled trial

Study objectives
Please note that as of 24/04/2008 this record was extensively updated due to the omission of the aripiprazole arm from this study after a discussion with the ethical committee. All updates can be seen under the relevant field, under the update date of 24/04/2008. The previous title of the trial was 'Aripiprazole and methylphenidate in the treatment of amphetamine dependence: a double-blind randomised, placebo-controlled trial'. The following changes have also been made:
1. The anticipated end date of this trial was extended to 31/12/2009, the previous anticipated end date was 31/12/2007
2. The current target number of participants has been changed to 140, the previous target number of participants was 210

Current hypothesis as of 24/04/2008:
To study if methylphenidate is more effective than placebo in reducing amphetamine use.

Previous hypothesis:
To study if aripiprazole or methylphenidate is more effective than placebo in reducing amphetamine use.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. Finland: Ethics Committee for Paediatrics, Adolescent Medicine and Psychiatry, Hospital District of Helsinki and Uusimaa on the 18th October 2005 (ref: 79/D7/2005)
2. New Zealand: Northern X Regional Ethics Committee, Auckland on the 8th October 2007

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
Current interventions as of 24/04/2008:
Methylphenidate SR 54 mg/d or placebo. Duration of treatment and follow-up was 22 weeks.

Previous interventions:
Aripiprazole 15 mg/d or methylphenidate SR 54 mg/d or placebo.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
Current primary outcome measure(s) as of 24/04/2008:
1. Proportion of positive amphetamine (methamphetamine) urine samples (intention-to-treat [ITT] analysis; all missing samples considered as positive)
2. Quantitative amphetamine/methamphetamine urine analysis (ITT analysis)

Previous primary outcome measure(s):
Proportion of positive amphetamine (methamphetamine) urine samples (intention-to-treat analysis; all missing samples considered as positive).

Secondary outcome measures
Retention in treatment.

Overall study start date
01/03/2004

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Amphetamine (or methamphetamine) dependence (Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition [DSM-IV])
2. Aged between 18 - 65 years, either sex
3. Recent and accustomed amphetamine (methamphetamine) use (urine analysis positive)

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
140

Key exclusion criteria
Current exclusion criteria as of 24/04/2008:
1. Simultaneous participation in other treatment (intervention) studies
2. Uncontrolled use of other substances (e.g. alcohol) requiring medical treatment
3. Some other substance than amphetamine/methamphetamine as the primary drug
4. Another significant mental disorder or risk of suicide
5. Mental disorder which needs special treatment
6. Significant brain, thyroid, renal, gastrointestinal or cardiovascular disease
7. Epilepsy
8. Glaucoma
9. Tourette disorder or tics
10. Clinically significant liver disease
11. Female gender without adequate pregnancy prevention
12. Pregnancy
13. Previous methylphenidate abuse

Previous exclusion criteria:
1. Simultaneous participation in other treatment (intervention) studies
2. Having other native language than Finnish
3. Uncontrolled use of other substances (e.g. alcohol) requiring medical treatment
4. Some other substance than amphetamine/methamphetamine as the primary drug
5. Another significant mental disorder or risk of suicide
6. Mental disorder which needs special treatment
7. Significant brain, thyroid, renal, gastrointestinal or cardiovascular disease
8. Epilepsy
9. Glaucoma
10. Tourette disorder or tics
11. Clinically significant liver disease
12. Female gender without adequate pregnancy prevention
13. Pregnancy
14. Previous methylphenidate abuse

Date of first enrolment
01/03/2004

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Finland

New Zealand

Study participating centre
Niuvanniemi Hospital
Kuopio
Finland
FI-70240

Sponsor information

Organisation
University of Kuopio (Finland)

Sponsor details
c/o Jari Tiihonen
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Sponsor type
University/education

Website
http://www.uku.fi/english/

ROR
https://ror.org/00cyydd11

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Current sources of funding as of 24/04/2008:

Funder Name
University Hospital of Helsinki (Finland) - 67,000 Euros

Funder Name
National Public Health Institute (Finland) - 123,500 Euros

Funder Name
Niuvanniemi Hospital (Finland) - 30,000 Euros

Funder Name
Department of Forensic Medicine, Faculty of Medicine, University of Helsinki (Finland) - 15,000 Euros

Funder Name
Academy of Finland (Finland) - 81,000 Euros

Funder Name
Total: 316,500 Euros

Funder Name
Previous sources of funding:

Funder Name
University Hospital of Helsinki (Finland) - research assistant: 24,000 Euros; basic laboratory analysis: 13,000 Euros; randomisation and drug capsulation: 30,000 Euros

Funder Name
National Public Health Institute (Finland) - drug analysis: 67,000 Euros; database and statistics: 123,500 Euros

Funder Name
Niuvanniemi Hospital (Finland) - 30,000 Euros

Funder Name
Department of Forensic Medicine, Faculty of Medicine, University of Helsinki (Finland) - 15,000 Euros

Funder Name
Total: 235,500 Euros

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	Interim results	01/01/2007		Yes	No