The relationship between clinical efficacy and efficacy as measured by two versions of the Continuous Performance Test of OROS-Methylphenidate in adults with ADHD: a double blind placebo controlled medication trial.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Psychiatric disorders NEC
Study type	Interventional

Summary

ID

NL-OMON31400

Source
ToetsingOnline

Brief title
CPT and OROS-Mph in adults with ADHD

Condition

- Psychiatric disorders NEC

Synonym
ADHD

Research involving

Human

Sponsors and support

Primary sponsor: Parnassia (Den Haag)
Source(s) of monetary or material Support: Kenniscentrum ADHD bij volwassenen

Intervention

Keyword: ADHD, Continuous Performance Test, inhibition, OROS-methylphenidate

Outcome measures

Primary outcome

Clinical response to medication:

• ADHD Rating Scale (self report)

• Clinical Global Impression (CGI-Improvement; investigator based)

Clinical response is defined as: decrease of at least 2 points on the CGI and a

decrease in complaints on the ADHD Rating Scale of at least 30 %

CPTs

For both CPTs the following dependent variables will be compared:

1. Omission errors

Missed goal stimuli, a measure of sustained attention/ vigilance

2. Commission errors

Reponse to non-goal stimulus: a measure for impulsivity/ inhibition

3. Mean hit reaction time

Measure of the latency of the response execution proces

4. Standard deviation of mean hit reaction time

Measure for consistency of responses

5. *attentiveness* (d*)

Derived from signal detection theory: a measure for distinction between goal

and non-goal stimuli

6. *risk taking* (β)

Derived from signal detection theory: measure of response style (cautious

version impulsive)

Secondary outcome

Not applicable.

Study description

Background summary

Attention Deficit Hyperactivity Disorder (ADHD) is a disorder that leads to serious symptoms and impairment in children as well as adults. Treatment of choice is methylphenidate. Until recently, only a short acting version of this drug was available, but a long acting version that only has to be taken once a day is now available (OROS-methylphenidate; OROS-MPh). This leads to better treatment adherence, but still adults with ADHD show problems with adherence to their medication because it is hard for them to evaluate their own improvements due to their attention deficit. This causes large clinical needs for an objective measurement of improvement with medication. A suitable candidate for this may be found in the Continuous Performance Test (CPT), a computerized test for attanion and inhibition. Several versions of this test are now commercially available, two of which will be compared in this study.

Study objective

The main objective of the study is to find an instrument that can be used to objectively establish improvement in adults with ADHD with treatment with OROS-Mph, so that adherence to treatment can be increased and so that patients and docters can objectively see improvement when there is doubt about the effects of treatment. Further goals are connecting clinical response and response on the CPT with OROS-Mph to certain genetic polymorphisms that have

been associated with ADHD.

Study design

Double blind cross-over placebo controled random trial.

Intervention

1 week lead-in OROS-Mph (36 mg)
1 week OROS-Mph (72 mg)
1 week wash-out
1 week lead-in placebo (36 mg)
1 week placebo (72 mg)

or vice versa (related to cross over design)

Study burden and risks

Risks are minimal.
The burden for participants is six visits to the clinic. Each visit has a mean duration of half an hour.

Contacts

Public
Parnassia (Den Haag)

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2593 HR Den Haag
NL
Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

ADHD-combined subtype has been diagnosed according to regular clinical diagnostic procedures
Age 18-55
Patient is able to read and understand Patient Information
Patient has signed Informed Consent Form
Patient is able and willing to fill out questionnaires
Patient is able and willing to meet follow up appointments for the study

Exclusion criteria

- Comorbid disorder (Axis I) that is very severe at intake and that may interfere with need of rapid treatment or with the goals of the study:
Psychosis
Severe current substance abuse or substance dependence (alcohol: more than 2 consumptions per day or for women more than 15 consumptions in total per week or for men more than 21 conusmptions in total per week. Cannabis: more than one joint per day. Hard drugs: exclusion per se);Anxiety and/or mood disorders will be treated with SSRIs before treatment for ADHD starts.;- Use of the following medications within a month prior to participation to the study: stimulants, anti-psychotic medication, clonidine, benzodiazepines, beta-blockers;- Symptoms of dementia, amnestic disorders or other cognitive disorders;- Symptoms of serious Cluster B Axis II psychopathology that may interfere with cooperation to the study;- For women: pregnancy, breastfeeding of lack of suitable contraception;- Mental retardation;- Insufficient fluency in the Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2007
Enrollment:	44
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Concerta
Generic name:	OROS-methylphenidate
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	15-05-2007
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

Approved WMO

Date:	28-09-2007
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2007-001294-28-NL
CCMO	NL16911.097.07