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The Continuous Performance Test (CPT) study: OROS-methylphenidate efficacy on objective measures

Submission date
18/06/2013

Recruitment status
No longer recruiting

Registration date
02/07/2013

Overall study status
Completed

Last Edited
09/08/2019

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Research shows that attention deficit hyperactivity disorder (ADHD) patients have difficulty reporting on their own ADHD symptoms and tend to under report their symptoms. This problem also occurs when reporting on the effects of the drug methylphenidate on their ADHD symptoms. The stimulant drug methylphenidate is the preferred treatment for ADHD, with 50-70% of ADHD patients responding well to treatment. An objective test (a test in which the feelings or opinions of the person marking it cannot affect the results) instead of subjective self-reports may be a new and reliable method for measuring medication effects in ADHD patients. This study aimed to find out about the effects of the long-acting stimulant methylphenidate (OROS-methylphenidate) on the performance of two objective Continuous Performance Tests (CPTs) among adults with ADHD.

Who can participate?
Twenty two individuals aged 18-55 years with a diagnosis of the combined subtype of ADHD were recruited (17 males and 5 females).

What does the study involve?
The study compared OROS-methylphenidate treatment to a placebo (dummy). All participants received both OROS-methylphenidate and placebo in a randomly allocated order: they either received placebo during the first treatment period and OROS-methylphenidate during the second treatment period, or they received OROS-methylphenidate during the first treatment period and placebo during the second treatment period.

What are the possible benefits and risks of participating?
Participants directly benefit from the study by experiencing the effectiveness of OROS-methylphenidate on their ADHD symptoms. Indirectly, beneficial effects of OROS-methylphenidate on objective measures give physicians a tool to investigate medication effects without inclusion of subjective patient reports. Use of OROS-methylphenidate may be

associated with side effects, of which insomnia, decreased appetite, weight loss, headache, palpitations, nervousness, dizziness, irritability, anxiety, gastrointestinal problems, dry mouth, tics or involuntary movements, euphoria and sadness are seen in 1-10% of patients.

Where is the study run from?
The CPT study has been set up by the PsyQ Expertise Center Adult ADHD in The Hague, The Netherlands.

When is the study starting and how long is it expected to run for?
The study inclusion started in November 2007 and the last participant ended the study in July 2010. The total duration of the trial was almost 3 years. The number of eligible patients for the study was smaller than expected.

Who is funding the study?
This study was financially supported by the Parnassia Bavo Academy (PBA) Stimulation Fund (Stimuleringsfonds), Netherlands.

Who is the main contact?
Dr Annet Bron, PhD student/psychologist
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2007-001294-28

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
n/a

Study information

Scientific Title

Efficacy of OROS-methylphenidate on specific executive functioning deficits in adults with Attention deficit hyperactivity disorder (ADHD)

Acronym
CPT

Study objectives
It was hypothesized that the efficacy of OROS-methylphenidate over placebo could be assessed by using objective measures, that reflected the underlying executive functioning deficits present in patients with ADHD.

The null hypothesis was that there were no differences between treatment groups, indicating that OROS-methylphenidate effects would better be investigated with subjective measures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Dutch Medical Ethics Committee (METiGG) 15 May 2007, ref: 7208
2. Dutch Central Committee on Research Involving Human Subjects (CCMO) 15 May 2007, ref: NL16911.097.07

Study design
Randomized double-blind placebo-controlled cross-over study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Attention Deficit/Hyperactivity Disorder

Interventions
The total duration of the study period was 6 weeks. The first week was the baseline measurement (medication-naïve), the second and third week constituted the first treatment period, the fourth week was the wash-out week, and the fifth and sixth week contained the second treatment period.

Participants were randomized for medication order: they received either placebo during first treatment period and OROS-methylphenidate during second treatment period, or OROS-methylphenidate during first treatment period and placebo during second treatment period. The dosage of the OROS-methylphenidate was titrated to a once daily dose of 36 milligrams in the first week of the treatment period (week 2 or 5), in order to get participants used to OROS-methylphenidate effects. This is called the lead-in dose. OROS-methylphenidate was up-titrated to a once daily dose of 72 milligrams in the second week of the treatment period (week 3 or 6). All participants were instructed to take the study medication at 8 am, in order to have optimal methylphenidate plasma concentration during the CPT task, which was conducted 1,5 hours later, on the last day of the treatment period.

The study comprised of 6 weeks including the following time points: baseline (week 1; medication-naïve), lead-in dose of 36 mg placebo medication (week 2), test dose of 72 mg placebo medication (week 3), wash-out week (week 4), lead-in dose of 36 mg OROS-methylphenidate (week 5), and test dose of 72 mg OROS-methylphenidate (week 6).

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
OROS-methylphenidate

Primary outcome measure
Objective efficacy of medication on five parameters of the Conners Continuous Performance Test (C-CPT) and Test of Variables of Attention (TOVA): Hit Reaction Time (HRT), Reaction Time Variability (RTV), Omission Errors (OE), Commission Errors (CE), and D-Prime (DP).

The primary outcomes were measured at baseline, after using 72mg of placebo medication, and after using 72mg of OROS-methylphenidate, that is, at the end of week 1, week 3 and week 6.

Secondary outcome measures
1. Subjective efficacy as measured by the number of ADHD symptoms using the ADHD-Rating scale
2. Adherence to medication using the Adherence Questionnaire
3. Side effects of medication using the Side Effects Rating Scale

The secondary outcomes were tested every week in order to monitor the well-being and adherence of the participants, but only considered for analyses in week 1, week 3 and week 6 (i. e., at baseline, after using 72mg of placebo medication, and after using 72mg of OROS-methylphenidate).

Overall study start date
01/11/2007

Completion date
11/02/2010

Eligibility

Key inclusion criteria
1. Between 18-55 years of age. The participants are of either sex. We included 22 adults with the combined subtype of ADHD, of which 17 were male and 5 were female.
2. Diagnosis of ADHD, combined subtype

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Both

Target number of participants
22

Total final enrolment
22

Key exclusion criteria
1. Having severe comorbid psychiatric disorders at time of the study screening (as measured by the Structured Clinical Interview for DSM disorders; SCID)
2. Receiving treatment with stimulants, antipsychotics, clonidine, benzodiazepines, or beta-blockers <1 month before study participation
3. Having any cognitive disorder like dementia or amnesic disorder
4. Mental retardation
5. Being pregnant or nursing

Date of first enrolment
01/11/2007

Date of final enrolment
11/02/2010

Locations

Countries of recruitment
Netherlands

Study participating centre

Carel Reinierszkade 197
The Hague
Netherlands
2593 HR

Sponsor information

Organisation
Parnassia Bavo Academy (PBA) (Netherlands)

Sponsor details
Department of Scientific Research
Monsterseweg 83 H
The Hague
Netherlands
2553 RJ

Sponsor type
University/education

Website
http://www.parnassia-academie.nl

ROR
https://ror.org/002wh3v03

Funder(s)

Funder type
University/education

Funder Name
Parnassia Bavo Academy (PBA) (Netherlands) - Stimulation Fund (Stimuleringsfonds; ref: SF-2012/RK/ns)

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	01/04/2014	09/08/2019	Yes	No