The effects of long-acting methylphenidate on academic activity and related constructs in children with ADHD: A randomised placebo controlled trial

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See page 9Primary Objective:The primary objective of this study is to explore the relationship between MPH and academic activity and the mediating roles of ADHD behaviours, cognitive deficits and motivational deficits in this relationship. Therefore…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Psychiatric and behavioural symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON37537

Source
ToetsingOnline

Brief title
ADHD and medication in the classroom

Condition

- Psychiatric and behavioural symptoms NEC

Synonym
ADHD, hyperkynetic syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Shire,Shire Pharmaceuticals

Intervention

Keyword: Academic activity, ADHD, Methylphenidate, motivation

Outcome measures

Primary outcome

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The primary outcome measure for academic activity consists of measures for academic productivity (effort and engagement) and academic ability:

1. Academic productivity will be assessed by means of observation (the amount of on-task behaviour) by a trained observer according to standardised rating forms. In addition, percentage of completed assignments for the tests for mathematics and spelling (see below) will be calculated as a measure of productivity.

2. Academic ability will be assessed with a range of tests witch excellent psychometric properties. As children with ADHD particularly experience problems with mathematics, reading and spelling, these academic skills will be the focus of our assessment. For reading ability technical reading, syntactic technical reading and syntactical reading of stories are separately assessed.

Three putative mediating variables will be measured:

3. ADHD behaviours. We will use a set of well-established behavioural rating scales to assess day-to-day behavioural effects of MPH on the child including the Child Behavior Checklist (CBC) and Teacher Rating Form(TRF) (Achenbach & Edelbrock, 1981), the VvGK (Oosterlaan et al., 2000), the ADHD rating-scale (DuPaul, 2007) and the Strengths and Weakness of ADHD-symptoms and Normal Behavior rating scale (SWAN; Hay, Bennett, Levy, Sergeant, & Swanson, 2007; Swanson et al., 2005). Both parents and teachers are required to fill out these rating scales measuring core ADHD and oppositional defiant (ODD) and conduct disorder (CD) symptoms. In the interest of the cross-over design, adapted versions are used that are suitable for repeated administration. As children with ADHD are often hyperactive en therefore have an above-average mobility actigraphy will be used to objectively measure mobility and sleep-wake rhythm of children during the experimental conditions. Actigraphy is sensitive to the effects of MPH (Boonstra et al., 2007) and provides additional information to behavioural rating scales (Uebel et al., 2010).

4. Cognitive deficits. Cognitive performance is assessed by a measure of estimated total IQ, measures of executive functioning including inhibitory control, verbal and visual working memory, and attention (core executive functioning deficits, see Willcutt et al., 2005), sensory integration and measures of learning ability. Total estimated time for cognitive neuropsychological tests is 60 minutes.

5. Motivational deficits. The third level of assessment concerns motivational deficits. Motivational deficits are assessed with measures of delay aversion and reward sensitivity, intrinsic motivation and extrinsic motivation. Delay aversion and extrinsic motivation are assessed with neuropsychological tasks. For intrinsic motivation, rating scales are filled out by the child, parent and teacher. Total estimated time for the motivational measurements is 30, including time necessary for the questionnaires.

Secondary outcome

not applicable

Study description

Background summary

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ADHD is a chronical developmental disorder. On average, one child out of every two elementary school classes is diagnosed with ADHD. Most of these children have comorbid learning problems or suffer from educational underachievement. Methylphenidate (MPH) is the most commonly prescribed treatment for ADHD. Research has proven the clinical effectivity of MPH for symptom reduction and improved cognition. The effects of MPH on academic activity are less well documented and nothing is currently known about processes mediating these effects. Given de commoness of learning problem in children with ADHD it is important to acquire more knowledge about the effects of MPH on academic activity. Prior research has shown that MPH can reduce ADHD behavioral symptoms and cognitive impairments (MTA study, 1999). No differences were found between short-acting and long-acting MPH (Schachar et al., 2008; Swanson et al., 2004) but the number of studies is limited. Even though MPH acts upon the dopamine networks little is known about the effects of MPH on motivational problems in children with ADHD.

Study objective

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Primary Objective:
The primary objective of this study is to explore the relationship between MPH and academic activity and the mediating roles of ADHD behaviours, cognitive deficits and motivational deficits in this relationship. Therefore, the direct effects of MPH on ADHD behaviours, cognitive deficits and motivational deficits are taken into account. In particular, evidence on the effects of MPH on motivational deficits in ADHD is scarce. It is hypothesized that treatment with MPH results in increased academic activity as compared to placebo control. If MPH improves academic activity, comparisons with the control group will be made to see if academic activity in children with ADHD normalises when treated with MPH.

Secondary Objectives:
Secondary objectives are to explore the relation between academic effort and engagement and academic ability, resulting in a clearer description of the construct of academic activity which is a frequently used outcome variable in many clinical studies. Furthermore, the relation between behaviour, cognition, motivation and academic activity will be studied in children between 8-13 years old. A comparison between children with ADHD and healthy controls will be made to investigate whether the relationship between these variables differs between these groups.

Study design

The study design is a randomised placebo-controlled cross-over design. Each condition (Equasym versus placebo) lasts one week.

Intervention

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In the placebo-condition the participants will take a placebo-capsule every morning for one week. In the medication-condition participants will take a capsule with Equasym XL every morning for one week. Testing takes place at the last day of both week. Before and between the test weeks a washout period (2-4) is scheduled. When the participants regular medication consists of short-acting MPH, this dose will be converted to the optimal dose for long-acting MPH (see Banachewski et al., 2002). The optimal clinical dose has been determined at the time of medication prescription, either with a double-blind placebo-controlled trial or with by slowly increasing the dose until an optimal behavioral effect with minimal side effects is reached.

Study burden and risks

No risks associated with participation to our study are known. Participants receive their regular dose of medication or a converted dose of MPH in a

different formulation. During the placebo condition the participants receive no medication. For this study every participant will be tested twice (at the end of each condition) for 90-120 minutes. To minimize inconvenience, testing takes place at the primary school of the participant. Therefore, no extra time invested needs to be made by the parents and no additional traveling is required. In addition, short questionnaires will be filled in by the parents and teacher of the participant and the participant will be observed in the classroom for a short time period (8 minuten).
In general, experience learns that most children enjoy the computerized tests that look like computer games. To assure that testing does not interfere with the school program, a suitable testing time is chosen in consultation with the teacher.

Because many children with ADHD between 8-13 years of age experience problems at school and many of these children are treated with MPH it is important for these children and their parents to know more about the the effects of MPH on academic activity. Furthermore, additional knowledge on the effects of MPH on behavioral, cognitive and motivational deficits in ADHD are important, also to improve treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Patients: Children with ADHD will be included if they (1) are diagnosed with ADHD, (2) are currently treated with methylphenidate to reduce ADHD symptoms, (3) are aged between 8 and 13, (4) have an IQ > 70, and (5) the children and their parents have sufficient knowledge of the Dutch language;Control group: Children will be included if they are (1) aged between 8-13 years, and (2) attend regular primary school

Exclusion criteria

The following exclusion criteria will be applied for the patient group: (1) medication other than methylphenidate, (2) psychiatric disorder(s) other than ADHD and oppositional defiant disorder (ODD) conduct disorder (CD), anxiety disorder and learning disorder and, (3) neurological impairments.;For the control group children will be excluded if they have psychiatric or neurological problems.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-01-2013
Enrollment:	100
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Equasym XL
Generic name:	methylphenidate hydrochloride
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	12-03-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-10-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	EUCTR2012-000492-17-NL
CCMO	NL39440.029.12