International Study for the Prediction of Optimized Treatment - in ADHD

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cognitive and attention disorders and disturbances
Study type	Observational non invasive

Summary

ID

NL-OMON33496

Source
ToetsingOnline

Brief title
iSPOT-A

Condition

- Cognitive and attention disorders and disturbances

Synonym
ADHD, Attention Deficit/Hyperactivity Disorder

Research involving
Human

Sponsors and support

Primary sponsor: Brain Resource Company
Source(s) of monetary or material Support: Brain Resource Company Operations

Intervention

Keyword: ADHD, biomarkers, methylphenidate, Personalized Medicine

Outcome measures

Primary outcome

The primary aim of this study is to establish objective and reliable markers for diagnosis and treatment evaluation. To this aim, treatment response will not simply be measured by change in clinical rating (e.g. Conners), but also through normalization (change from outside to within normal range) of baseline differences in markers. As a complement to previous research using clinical symptoms, markers that improve concurrently with clinical symptoms will be identified through correlation analyses.

Secondary outcome

NA

Study description

Background summary

ADHD is a common psychiatric disorder in children and adolescents and typically has severe consequences for the individual, including difficulties in school or work, increased risk of drug abuse and severe accidents. It also commonly impacts on the family and surrounding community, including a significant financial cost for treatment and familial stress and breakdown.

A large majority of ADHD individuals (75-90%) are treated with stimulant medication at some stage of the disorder. Yet, the use of stimulants has been associated with significant disadvantages in terms of efficacy, potential safety and public perception. It has been reported that up to 30% of ADHD patients do not respond positively to stimulants. Thus, there is a need to identify objective markers of stimulant efficacy.

Study objective

The primary objectives of the iSPOT-A trial are to use Brain Resource's standardized 'Integrative Neuroscience' test batteries to 1) Identify objective markers of ADHD compared with healthy controls, using cognitive, brain and genetic markers
2) Identify objective markers that best predict treatment response (defined by active symptom remission) to methylphenidate (immediate release formulation) using cognitive, brain and genetic markers.

Study design

This is an open-label study. A control group constitutes of healthy controls.

Study burden and risks

There is a time investment of two times 5-6 hours of assessments at Brainclinics (psychological interview, questionnaires, QEEG and neuropsychological assessment, collection of saliva, tox/preganancy test) as well as two times clinical monitoring (telephone interview and questionnaires) of around 40 minutes of duration.

The risks of the study procedure are limited to possible skin irritation as a result of Quickgel use for the EEG assessment.

The treatment of ADHD with short-acting methylphenidate can cause a variety of side-effects. The research staff will discuss this with the parents and children. However, since it concerns treatment as usual, the side-effects are not associated with the procedures of the study itself.

There are no direct benefits for subjects who participate. However, parents and teachers can get a standardized Conners report will which shows course of symptoms over the time and which can demonstrate improvement/non improvement as a result of 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

ADHD subjects only: meet DSM-IV criteria for primary diagnosis of ADHD at study entry, ADHD-RS IV score >/ 6 for inattention and/or hyperactivity-impulsivity, candidate for methylphenidate, stimulant naive or stimulant free
All subjects: males and females between 6-17 years of age, fluent and literate in Dutch or English, signed an informed consent or assent form where required and/or whose parent or legal guardian has provided written informed consent

Exclusion criteria

ADHD subjects only: known contra-indication to the use of methylphenidate, prior treatment with methylphenidate or any other stimulant medication in the past 7 days, known history of hypersensitivity and/or anaphylaxis to methylphenidate
Control subjects only: current or previous diagnosis of ADHD or any other psychiatric diagnosis, prior treatment with methylphenidate
All subjects: pregnancy of child bearing potential who are not using a form of contraception and are at risk of becoming pregnant during the study, known medical condition, disease or neurological disorder which might interfere with the assessment to be made in the study or put ADHD patients at increase risk when exposed to the optimal doses of the drug treatment, history of physical brain injury or blow to the head that resulted in loss of consciousness of greater than 5 minutes, known past or present substance dependence including alcohol, participation in an investigational study within four months of the baseline visit in which subjects have received an experimental drug/device that could affect the primary end points

of this study, subjects who have a severe impediment to vision, hearing and/or hand movement, which is likely to interfere with their ability to complete the testing batteries, subjects who are unable and/or unlikely to comprehend and follow the study procedures and instructions, presence of any other co-morbid primary DSM IV disorders

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-10-2009
Enrollment:	124
Type:	Actual

Medical products/devices used

Registration:	No
Product type:	Medicine
Brand name:	Ritalin
Generic name:	methylphenidate
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	06-07-2009
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	28-06-2011
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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	EUCTR2009-013272-47-NL
ClinicalTrials.gov	NCT00863499
CCMO	NL28450.072.09

Study results

Date completed:	01-05-2019
Results posted:	23-05-2019
Actual enrolment:	194

Summary results
Trial is onging in other countries

First publication

01-01-1900