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Prediction of medication response in children with Attention Deficit Hyperactivity Disorder (ADHD): Electroencephalogram (EEG) differences between responders and non-responders to methylphenidate

Submission date 16/07/2007	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 16/07/2007	**Overall study status** Completed	
Last Edited 27/10/2021	**Condition category** Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil Known

Protocol serial number
P06-160C, NL969 (NTR996)

Study information

Scientific Title
Prediction of medication response in children with Attention Deficit Hyperactivity Disorder (ADHD): Electroencephalogram (EEG) differences between responders and non-responders to methylphenidate

Study objectives
The EEG profile in responders to methylphenidate will be differ from the EEG profile in non-responders to methylphenidate (i.e., higher total power, increased theta/beta ratio and theta /alpha ratio).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Clinical trial

Primary study design
Interventional

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Medication response in children with Attention Deficit Hyperactivity Disorder (ADHD)

Interventions
Methylphenidate 10 mg.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome(s)
Primary outcome measure is the absolute and relative power in different frequency bands of the EEG.

Key secondary outcome(s))
1. Event-related potentials in response to the stop-task and Continuous Performance Test (CPT)
2. EEG coherence
3. Scores on the Spatial Span (SSP) task and Spatial Working Memory (SWM) task from the Cambridge Neuropsychological Test Automated Battery (CANTAB)
4. Gene polymorphisms of the dopamine D4 receptor (DRD4), dopamine transporter (DAT1), and serotonin transporter (5-HTT)
5. Scores on the 18-item Swanson, Nolan and Pelham Teacher and Parent Rating Scale (SNAP-IV)

Completion date
31/08/2007

Eligibility

Key inclusion criteria
1. Diagnosed with ADHD combined type (no primary diagnoses of attention deficit) according to Diagnostic and Statistic Manual of mental disorders - fourth edition - criteria (DSM IV, APA 1994)
2. They have (no history of) anxiety disorder, depression, tics, psychosis or autism
3. Their age is ranged between 7 and 12
4. Intelligence Quotient (IQ) is above 75
5. They are free from psychoactive medication
6. They are free from methylphenidate at least 48 hours before testing
7. They have no known cardiovascular disease
8. Normal static binocular acuity, corrected or uncorrected
9. Written informed consent from the parents

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
7 years

Upper age limit
12 years

Sex
Not Specified

Key exclusion criteria
1. IQ is below 75
2. One or more of the following co-morbid disorders are diagnosed:
2.1. Anxiety disorder
2.2. Depression
2.3. Tics

2.4. Psychosis
2.5. Autism
3. Prior enrolment in the same study
4. Participation in another clinical trial simultaneously
5. Familiar with epileptic disorders
6. Long term usage of methylphenidate (greater than three months)

Date of first enrolment
25/05/2007

Date of final enrolment
31/08/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Utrecht Institute for Pharmaceutical Sciences
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Sponsor information

Organisation
Utrecht Institute for Pharmaceutical Sciences (The Netherlands)

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Research organisation

Funder Name
Utrecht Institute for Pharmaceutical Sciences (The Netherlands)

Results and Publications

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

IPD sharing plan summary
Not provided at time of registration