

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 16/07/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 27/10/2021	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil Known

Secondary identifying numbers

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

Secondary study design

Single-centre

Study setting(s)

Hospital

Study type(s)

Not Specified

Participant information sheet**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 measure

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

Secondary outcome measures

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)

Overall study start date

25/05/2007

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

Age group

Child

Lower age limit

7 Years

Upper age limit

12 Years

Sex

Not Specified

Target number of participants

50

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

Utrecht

Netherlands

3584 CA

Sponsor information**Organisation**

Utrecht Institute for Pharmaceutical Sciences (The Netherlands)

Sponsor details

Utrecht University

P.O. Box 80082

Utrecht

Netherlands
3508 TB

Sponsor type

Research organisation

Website

<http://www.pharm.uu.nl/ffwuk.htm?/uips/>

ROR

<https://ror.org/04pp8hn57>

Funder(s)

Funder type

Research organisation

Funder Name

Utrecht Institute for Pharmaceutical Sciences (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration