QEEG measurements to help identify developmental disorders in children.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Developmental disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON36354

Source
ToetsingOnline

Brief title
QEEG profiles in developmental disorders

Condition

- Developmental disorders NEC

Synonym
developmental disorder; brain function disorder

Research involving
Human

Sponsors and support

Primary sponsor: Viecuri Medisch Centrum voor Noord-Limburg
Source(s) of monetary or material Support: BrainMarker B.V.,de kosten worden gedragen door de vakgroep kindergeneeskunde van VieCuri MC en BrainMarker B.V. ;welke laatste ook zorgt voor het ter beschikking stellen van de meetapparatuur en voor deskundigen op het gebied van QEEG. Subsidie wordt aangevragd bij de Hersenstichting en

bij Stichting De Weijerhorst (Maastricht)

Intervention

Keyword: ADHD, Autism, brain, developmental disorders, QEEG

Outcome measures

Primary outcome

QEEG measurements will be performed under four conditions in every participant:

resting condition eyes open, resting condition eyes closed, during an attention

task and during a motor task . QEEG profiles will be the main outcome measures.

Secondary outcome

Not applicable

Study description

Background summary

Diagnosing developmental disorders is a time consuming process. Until now, QEEG measurements are not used in this process although QEEG profiles have proven to be reliable indicators of different psychopathologies. Several studies have shown that brain activation patterns of children with developmental disorders like ADHD and ASD can be differentiated from brain activation patterns of control children. Unfortunately different researchers use different equipment, software and measurement settings. Because QEEG outcomes are very dependent on these factors, data across studies and across studied groups cannot always be compared.

Study objective

The main aim of this research is to search for sensitive and specific QEEG markers to differentiate between children with a developmental disorder, in this case ADHD and ASD, and a control group and to differentiate between these two developmental disorders compared with each other. Besides this research will look for the influence on the QEEG of comorbidities that are of current interest like Gilles de la Tourette, dyslexia and DCD. To do so, the patient groups and the control group will be measured with the same equipment, software and measurement settings. In this way QEEG outcomes across groups can be

compared in a reliable and valid way.
By means of combining several (non)linear analysis methods QEEG markers for every pathology will be examined and developed and sensitivity and specificity measures of these markers will be calculated.
Additionally the effect of medication (methylphenidate) in children with ADHD on the QEEG profile will be investigated.

Study design

The nature of the study is observational.

Study burden and risks

The burden and risks of this research are very minimal. QEEG measurements are non-invasive measurements. Placing the electrodes on the scalp does not hurt and also the measurement itself is painless. The total time it takes for a child to participate does not exceed 45 to 60 minutes. If a child is using medication (methylphenidate) for ADHD, the research will be conducted twice; once with and once without medication. The total time for the research then comes to 90 to 120 minutes.
Measurements will be conducted with medically certified equipment (class 2A).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Boys between 6 and 12 years with the diagnosis of ADHD or ASD (autism spectrum disorder) conform DSM-IV criteria , with or without co-morbidities like Gilles de la Tourette, DCD or dyslexia.
Healthy boys between 6 and 12 years as controlgroup.

Exclusion criteria

Children with organic brain-defects, epilepsy, migraine, other psychiatric disorders than developmental disorders and children with influenza or fever.
Besides the boys in the controlgroup may not have any developmental disorders and should have normal results on the SDQ totalscore and subscores.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-04-2012
Enrollment:	110
Type:	Actual

Ethics review

Approved WMO Date:	07-06-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 24766
Source: NTR
Title:

In other registers

Register	ID
Other	candidate nr.9326 Ned.Trial Register
CCMO	NL29647.068.10
OMON	NL-OMON24766