Structural and functional connectivity in child psychiatric disorders

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

Summary

ID

NL-OMON39463

Source
ToetsingOnline

Brief title
Connectivity in Child Psychiatric disorders

Condition

- Developmental disorders NEC

Synonym
ADHD, attention deficit hyperactivity disorder, Autism, autism spectrum disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: FES (Fonds Economische Structuurversterking)

Intervention

Keyword: ADHD, Autism, Connectivity, MRI

Outcome measures

Primary outcome

The primary endpoints of this study are developmental changes in structural and functional brain connectivity. The measures of interest are resting-state functional connectivity, as assessed with resting-state functional Magnetic Resonance Imaging (rs-fMRI), myelination as assessed with Magnetization Transfer Imaging (MTI), and white matter integrity, as assessed with track-based Diffusion Tensor Imaging (DTI)-measures.

Secondary outcome

An exploratory analysis of the effect of genotype on shared risk genes for autism and ADHD will be conducted and symptoms of ADHD and ASD from symptom rating scales and performance on computerized tasks will be analyzed

Study description

Background summary

Recent MR-research has shown that brain connectivity changes over development. Furthermore, it appears that child psychiatric disorders may be associated with changes in connectivity. This protocol investigates structural and functional connectivity in children with child psychiatric diagnoses, in particular Autism Spectrum Disorders (ASD) and Attention Deficit/Hyperactivity Disorder (ADHD).

Study objective

Our primary objective is to investigate the development of structural and functional connectivity in autism and ADHD in comparison to the typical development of connectivity. A secondary objective is to investigate the

effects of ADHD and autism risk genes on brain connectivity in these disorders.

Study design

We propose to conduct a longitudinal MR-study to investigate the development of brain connectivity in ADHD and autism.

Study burden and risks

Participants will be asked to undergo an MRI-scan lasting approximately 45 minutes. DNA will be collected from saliva. MRI is a non-invasive technique, with no known risks associated with it. Subjects will be prepared for MR-scanning using an MR-simulation procedure. Incidental findings of structural cerebral pathology requiring medical treatment may occur. If this happens, the subject and his/her parents will be notified. No immediate benefits for subjects are to be expected from participation in this study. In the long run, increased understanding of the aetiology and pathophysiology of child psychiatric disorders may contribute to earlier diagnosis, and earlier detection and/or prediction of treatment outcome.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

General inclusion criteria for all subject groups
• Aged 6 through 18 years at initial inclusion
• Ability to speak and comprehend Dutch (both participant and parent).;Inclusion criteria for subjects with autism
• DSM-IV (APA, 1994) diagnosis of autism, supported by ADI-R interview;Inclusion criteria for subjects with ADHD
• DSM-IV (APA, 1994) diagnosis of ADHD, supported by DISC interview ;Inclusion criteria for control subjects
• No DSM-IV (APA, 1994) diagnosis, supported by DISC interview
• No history of psychiatric illness in first degree family members of the subjects

Exclusion criteria

1) Mental retardation (IQ < 70)
2) Major illness of the cardiovascular, the endocrine, the pulmonal or the gastrointestinal system
3) Presence of metal objects in or around the body (pacemaker, dental braces)
4) History of or present neurological disorder

Study design

Design

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

Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-10-2011
Enrollment:	600
Type:	Actual

Ethics review

Approved WMO Date:	02-09-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-09-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	08-03-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL33864.041.11