From Gene to Neural Function in ADHD. Enriching the Dutch Database of the International Multisite ADHD Genetics (IMAGE) Project.

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The overall aim of the study is to enrich the database of the Dutch IMAGE samples with (1) structural magnetic resonance imaging (sMRI) and functional MRI (fMRI) data; (2) follow-up data of clinical status (ADHD symptoms and relevant comorbidities)...

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

Summary

ID

NL-OMON32726

Source
ToetsingOnline

Brief title
From Gene to Neural Function in ADHD.

Condition

- Cognitive and attention disorders and disturbances

Synonym
ADHD, attention-deficit/hyperactivity disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: NWO

Intervention

Keyword: ADHD, genes, MRI, neuropsychology

Outcome measures

Primary outcome

Assessments will be scheduled 5 to 6 years after the baseline assessments. sMRI (30 min) and fMRI (60 min, while presenting the stop-task and a spatial working memory task) data will be acquired. Phenotyping will follow similar procedures as at baseline, and include a semi-structured investigator-based interview to categorically classify ADHD, and questionnaires to obtain dimensional scores of ADHD symptoms and related comorbidity. Outside the scanner, 8 other neuropsychological tasks will be administered to the children (set-shifting, verbal working memory, time reproduction, motor timing, motor control, motor speed, intelligence, and positive and negative reinforcement). Parents will be assessed using the same 10 neuropsychological tasks outside the scanner, and be phenotyped using questionnaires.

Secondary outcome

nvt

Study description

Background summary

Attention-deficit / Hyperactivity Disorder (ADHD) is a neuropsychiatric disorder which involves substantial involvement of genetic factors as indicated by adoption and twin studies. In the context of the International Multisite ADHD Genetics (IMAGE) project, an ongoing genetic initiative funded by the

National Institute of Mental Health in 2002, extensive phenotypic, endophenotypic (neuropsychological) and genotypic information of about 5758 subjects from 1401 ADHD families in 8 countries in Europe has been collected. A substantial subsample (1625 subjects from 388 families) of this database has been collected in the Netherlands by research groups in Nijmegen, Amsterdam and Groningen. The Dutch database also includes phenotypic and endophenotypic data from 271 healthy control children from 147 families. In 2006 the Genetic Association Information Network (GAIN) initiative of the National Institute of Health granted the IMAGE consortium the genotyping of 600,000 single nucleotide polymorphisms (SNPs) to perform a genome-wide association scan (GWAS) in 958 (315 from the Netherlands) trios of ADHD-affected children and their parents from the IMAGE cohort.

Study objective

The overall aim of the study is to enrich the database of the Dutch IMAGE samples with (1) structural magnetic resonance imaging (sMRI) and functional MRI (fMRI) data; (2) follow-up data of clinical status (ADHD symptoms and relevant comorbidities) using questionnaires and a semi-structured interview, and (3) neuropsychological endophenotypes of both probands and siblings of ADHD families and controls; in addition, (4) comparable phenotypic and neuropsychological endophenotypic data of the parents of children with ADHD and of control children will be collected. This resource will be made publicly available. By having access to the genotypes of the GWAS, this will allow us and other investigators to clarify the consequences of ADHD risk alleles at the level of both brain function and structure, to increase our understanding of the pathophysiology of ADHD, and to examine the role of genes in the persistence and outcome of ADHD over time.

Study design

Follow-up of ADHD and control cohort assessed between 2004 and 2006 to be re-assessed again between 2009 and 2011.

Study burden and risks

Discomfort associated with recalling psychiatric symptoms and MRI scanning (such as exposure to loud noise and being in a small closed space which may elicit claustrophobia) may be experienced. Some study subjects may benefit from early identification of previously unrecognized psychiatric illness or psychological deficits. Also in case anomalies are detected during MR scanning, parents or affected individuals, respectively, and their general practitioner will be alerted and all efforts will be made to assure diagnostic work-up and appropriate treatment.

Contacts

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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

Previous inclusion criteria: ADHD-families: at least one proband with the combined subtype of ADHD and at least one sibling and one parent available for testing. Children between the ages of 5 and 18 were included.
Control-children: no ADHD and no ADHD in their first-degree relatives. Children between the ages of 5 and 18 were included.;For the current follow-up: all children are contacted and tested again, regardless of previous in- and exclusion criteria allowing for studying remitted cases of ADHD (or new ADHD cases in the control group).

Exclusion criteria

(1) IQ<70, (2) a diagnosis of schizophrenia or autism that might confound the diagnosis of ADHD, and (3) neurological disorders such as epilepsy and brain injury, as well as any genetic or medical disorder associated with externalising behaviors that might mimic ADHD.

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2008
Enrollment:	1000
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL23894.091.08