Dysmorphic Features in Children with Autism Spectrum Disorders

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital and hereditary disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON29802

Source ToetsingOnline

Brief title Dysmorphism in autistic spectrum

Condition

- Congenital and hereditary disorders NEC
- Mental impairment disorders
- Psychiatric disorders NEC

Synonym

Pervasive developmental disorders (PDD)

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht **Source(s) of monetary or material Support:** Ministerie van OC&W

Intervention

Keyword: autism, dysmorphology, endophenotype, normal values

Outcome measures

Primary outcome

To try to classify autism, using clinical morphological examination, in

different subgroups in order to be able to predict prognosis more precisely.

Secondary outcome

Not applicable

Study description

Background summary

The effects of autism extend significantly beyond those afflicted by it. It also causes a heavy burden for their families and society, and it constitutes a big work load in child psychiatry. There is a number of studies that describe the prevalence of minor physical anomalies in children with autism, and in most of them the prevalence of minor anomalies was found to be increased. However, the available studies reported on relatively small patient samples which prevented reporting on the overall incidence of known syndromic entities within the study cohorts. Delineating subgroups in autism might give a more firm basis for predicting prognosis and might help to discover causes of specific subgroups.

Study objective

The purpose of the present study is to try to classify autistic children into distinct subgroups, by clinical morphological examination. We mainly want to answer the following questions: 1) Is there an increased prevalence of minor anomalies in autism? 2) If so, are determinable (patterns of) anomalies, related to specific subgroups of autism? 3) are sets of certain features/ anomalies related to specific phenotypic behavior characteristics in children with autism?

Study design

Clinical evaluation:

A physical examination will focus on dysmorphic features. It will be a surface examination: neither auscultation of the heart, nor abdominal palpation will be done. The examination will take 15 minutes, which does not constitute a significant burden for the children and parents. Clinical examination will include standard morphologic measurements of the face, ears, head, hands, and feet. (Hall et al.,1989; Aase,1990) Each child will be examined by the same physician (HMO), who is trained in the scoring of phenotypic findings. She had a training in dysmorphology (Merks et al., in press 2006). In the present study, 10 % of the subjects will be scored independently by the investigator (HMO) and an experienced clinical geneticist- pediatrician (FAB) also

Study burden and risks

There are no risks associated with morphological examination as only a physical examination is done. The technique is non-invasive and painless, and does not include the examination of genitals.

The collected data are used for research purposes only. The examination will take 15 minutes, which does not constitute a significant burden for the children and parents.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

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Eligibility criteria

Age

Adolescents (12-15 years) Adolescents (16-17 years) Children (2-11 years)

Inclusion criteria

Confirmed clinical diagnosis of autism or ASD made by a child psychiatrist based on DSM-IV criteria
Chronological age between 3 and 18 years

Exclusion criteria

Refusal to sign the informed consent (refusal to participate in the study)

Study design

Design

Study type:	Observational non 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):	15-10-2006
Enrollment:	300
Туре:	Actual

Ethics review

Approved WMO	
Date:	03-10-2006
Application type:	First submission
Review commission:	METC NedMec

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 CCMO ID NL11715.041.06