

Brain imaging of language function in autistic spectrum disorders

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The primary objective of this study is to identify the neural correlates of language functions and, in particular, abnormal pragmatic communication in autistic spectrum disorders.

Ethical review	Approved WMO
Status	Pending
Health condition type	Mental impairment disorders
Study type	Observational invasive

Summary

ID

NL-OMON30136

Source

ToetsingOnline

Brief title

Neuroimaging in autism

Condition

- Mental impairment disorders
- Developmental disorders NEC

Synonym

autism

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: autism, language, neuroimaging

Outcome measures

Primary outcome

The main outcome measures are ERP data and fMRI data.

Secondary outcome

none

Study description

Background summary

Autism Spectrum Disorders are severe and very persistent neuropsychiatric disorders which carry considerable burden for the patients, their families and for society. One of the major deficits in autism is the impaired language and understanding and use of social cues, which is called pragmatics. So far, no curative treatments of ASD are available. Research into the underlying neurobiology of ASD is critical to advance our knowledge of these disorders and, ultimately, in combination with other research strategies such as genetic studies, to develop more effective treatments.

Study objective

The primary objective of this study is to identify the neural correlates of language functions and, in particular, abnormal pragmatic communication in autistic spectrum disorders.

Study design

In this study between-subject comparisons will be made of the mentioned groups. After informed consent, in- and exclusion criteria will be checked. Cognitive functioning of healthy controls will be tested using 4 subtests of the WAIS. Patients and controls will be tested with EEG or fMRI.

A total number of 150 patients and 90 healthy control subjects will be recruited. Group size for fMRI will be 50 subjects with either high-functioning autism or Asperger disorder and 25 subjects with developmental language disorder. The control group will consist of 45 healthy subjects. For EEG the

group size will be 50 subjects with either high-functioning autism or Asperger disorder and 25 subjects with developmental language disorder, whereas the control group will include 45 healthy subjects.

Study burden and risks

The main burden for subjects participating in this protocol is the EEG and fMRI measurement. A subject will participate in either the EEG or the fMRI study, but not in both. EEG and fMRI are standardized procedures which carry no additional risks for harm or side-effects. However, fMRI is considered to be an invasive procedure. Therefore, we will perform fMRI measurements in accordance with the CCMO-MRI protocol as specified on the website of the CCMO.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

Autism or developmental language disorder; age 12-18

Exclusion criteria

1) sensory impairments, 2) neurological impairments, 3) experienced any neurological trauma, 4) metal objects in body (eg braces)

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:	Pending
Start date (anticipated):	01-05-2006
Enrollment:	240
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	NL11572.091.06