Unravelling the neurobiological basis of autism by looking into the auditory system

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Communication disorders and disturbances
Study type	Observational invasive

Summary

ID

NL-OMON31845

Source
ToetsingOnline

Brief title
Sound localisation in autistic subjects

Condition

- Communication disorders and disturbances

Synonym
autism, Autism spectrum disorder (ASD)

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Auditory Pathways, Autistic Disorder, Magnetic Resonance Imaging

Outcome measures

Primary outcome

1) Sound localisation performance data of autistic subjects

2) Structural MRI and fMRI data obtained during the sound localisation task in

the MRI scanner.

Secondary outcome

1) Finding indications for a specific neurobiological theory of autism

2) Testing the existing functional model of sound localisation in the auditory

system

Study description

Background summary

The neurological basis for autism is poorly understood. Reports on deficits in low-level sensory processing in subjects with autism as well as recent neuroimaging findings suggest a key role played by abnormalities in connectivity in the brain. The auditory system is relatively well-understood and consists of separate pathways that are involved in different aspects of sound localisation, making it an attractive target for investigating the role played by connectivity.

Study objective

The primary objectives of the study are
1) to determine whether sound localisation is impaired in autistic subjects and
2) to detect abnormalities in auditory sensory processing, and sound localisation in particular, at the neurobiological level in structural and functional MRI studies.

Study design

This study has a case-controlled cross-sectional design and consists of two experiments. In the first, the subjects' spatial auditory abilities will be comprehensively assessed. To this end, subjects will be seated in a dark, sound-attenuated room and instructed to point to various target auditory stimuli embedded in complex sound environments.

In the second experiment, simulated localised sounds will be presented over a headphone while the subject lies in the MRI scanner. The subject will be instructed to indicate the left-right position of the stimulus by pressing one of an array of buttons. While the subject performs the task, fMRI data will be collected. In addition to these functional data, resting state fMRI, and DTI data will be collected to study functional and structural connectivity.

In both experiments, the data obtained from the autistic subject population will be compared to the control group.

Study burden and risks

The proposed study does not include any invasive measures. The first experiment will consist of psychoacoustic measurements, for which no risks or side-effects are to be expected. In the second experiment, participants will undergo a one hour scanning session in the MRI scanner. This session is divided in two sessions of 30 minutes separated by a 15-minute break. The F.C. Donders Centre has a lot of experience with the type of research we are proposing in this protocol and there are no special risks associated with this kind of research. There will be no therapeutic benefit for the participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age between 18 and 35 years
- IQ above 85
- Right-handed
- Patients should meet DSM-IV criteria for autistic disorder or Asperger syndrome

Exclusion criteria

- Sensory impairments
- Neurological impairments such as seizure disorder
- Experienced any neurological trauma
- Used antipsychotics
- Severe (psychiatric) comorbidity
- Metal objects in their body.

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):	21-05-2010
Enrollment:	80
Type:	Actual

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	NL23644.091.08

Study results

Date completed:	09-11-2011

Actual enrolment:	42