Instrumental assessment of movement disorders in antipsychotic naive patients with autism and healthy controls

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Examine whether there are differences in both instrumental as well as clinical assessment of movement disorders among drug naive patients with autism compared with matched healthy controls.

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

Summary

ID

NL-OMON35557

Source
ToetsingOnline

Brief title
Movement disorders in autism

Condition

- Developmental disorders NEC

Synonym
Autism

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: antipsychotic naive, autism, Movement disorders

Outcome measures

Primary outcome

Difference in prevalences of instrumental assessment of movement disorders

among drug naive patients with autism compared with matched healthy controls

Secondary outcome

Difference in prevalences of clinical assessment of movement disorders among

drug naive patients with autism compared with matched healthy controls

Study description

Background summary

There is evidence that in autism repetitive and stereotyped behavior is related to an increase of the basal ganglia, particularly the Nucleus Caudatus. An interesting additional possibility is that other (mild) movement disorders (such as dyskinesia and parkinsonism ism) are also common in autism and possibly associated with the found structural abnormalities.

In addition, research shows that patients with autism are very sensitive to the development of movement disorders (dyskinesia and parkinsonism) after the use of antipsychotic drug, which is given in autism for the reason to reduce repetitive behavior.

Most likely these movements cannot only be attributed to antipsychotic drug use, but may form an integral part of the autistic syndrome and could be regarded as an endophenotype of the disease.

It is therefore essential that patients with autism who have never used antipsychotic medication be screened for the presence of these movement disorders (dyskinesia and parkinsonism). As these movement disorders are most likely to be mild, instrumental assessment must be used as it has proven to be more objective, reliable and sensitive than traditional rating scales.

Perhaps that in the future it can be better predicted which patients with

autism are vulnerable to the development of movement disorders after antipsychotic drug use.

Study objective

Examine whether there are differences in both instrumental as well as clinical assessment of movement disorders among drug naive patients with autism compared with matched healthy controls.

Study design

Case-control study

Study burden and risks

The assessment of the movement disorders takes about 30 minutes per person and can be held in a single research session. This research takes place in the department of Child- and adolescent psychiatry of the University Medical Centre Utrecht, the Netherlands. It includes non-invasive registration of movements by means of a computer task which is easy to handle and not burdensome and a non-invasive examination of the movements using clinical observation scales. There is no risk to the extent known, even for minors. For this study children and adolescents (6- 22 years) are included, because these groups are less likely to ever have used antipsychotics medication. Therefore the presence of possible movement disorders in antipsychotic patients with autism cannot be attributed to medication, but is related to the disorder itself and could be considered as a possible phenotype of autism. Participation in the study provides no direct benefit to the subjects itself. However, perhaps that in the future it can be better predicted which patients with autism are vulnerable to the development of movement disorders after antipsychotic drug use.

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

1. Patients with autism
-High functioning medication naïve patients diagnosed autism spectrum disorders according to DSM-IV codes 299.00 or 299.80
-Age 12-22 year: addendum 6-22;2. Healthy controls
Healthy controls without psychiatric disorders according to DSM-IV code V71.09
-Age 12-22 year; addendum 6-22

Exclusion criteria

-Use of antipsychotic medication, antidepressants or benzodiazepines, now or in the past.
-A medical, psychiatric (other than autism spectrum disorder) and / or neurological disorder (with the exception of epilepsy) that can produces movement disorders.
-DSM-criteria for substance abuse, other than nicotine of caffeine.
-IQ < 85; addendum IQ<70
-Participation of another medical study less than one month earlier
-Treatment with medication during the past 30 days that was not yet approved at the beginning of the study
-Severe life-threateningdisorders, if which the patients is most likley to die of within one year.

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):	02-08-2010
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	08-02-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-12-2010
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	NL29320.041.09