

Atomoxetine for Attention-deficit hyperActivity disorder Symptoms in children with pervasive developmental disorders: a pilot study

Submission date 26/02/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 26/02/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/03/2021	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NL407 (NTR447)

Study information

Scientific Title

Atomoxetine for Attention-deficit hyperActivity disorder Symptoms in children with pervasive developmental disorders: a pilot study

Acronym

AAAS

Study objectives

The aim of this study was to examine the tolerability and effectiveness of atomoxetine on Attention-Deficit/Hyperactivity Disorder (ADHD) symptoms and autistic features in children with pervasive developmental disorders.

Hypothesis:

Atomoxetine will be effective in reducing symptoms of inattention and overactivity in children and adolescents with Autism Spectrum Disorder (ASD).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Open label clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Attention Deficit Hyperactivity Disorder (ADHD), Pervasive Developmental Disorders

Interventions

Treatment with open label atomoxetine for ten weeks.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Atomoxetine

Primary outcome(s)

Change in the ADHD-Rating Scale-I (ADHDRS).

Key secondary outcome(s))

1. Clinical Global Impression Scale of improvement with regard to ADHD symptoms (CGI-ADHD-I)
2. The short form of the Conners Parent Rating Scale-Revised (CPRS-R)
3. The short form of the Conners Teacher Rating Scale-Revised (CTRS-R)
4. The Aberrant Behavior Checklist (ABC)
5. The Childrens Social Behaviour Questionnaire (CSBQ)
6. Nisonger Child Behavior Rating Form
7. Children's Yale-Brown Obsessive Compulsive Scale
8. Child Health and Illness Profile-CE
9. Cognitive Battery:
 - a. Wechsler Intelligence Scale for Children-III (WISC-III) Mazes
 - b. WISC-III Working Memory
10. Vineland Maladaptive Subscale
11. Safety measures:
 - a. routine lab
 - b. physical examination
 - c. Electrocardiogram (ECG)
 - d. open-ended questioning for adverse events

Completion date

20/10/2004

Eligibility

Key inclusion criteria

1. Males and females between the ages of at least six years of age and not more than 17 years of age at visit one
2. ASD (Diagnostic and Statistical Manual of Mental Disorders Fourth Edition [DSM-IV TR] diagnosis of autistic disorder or Aspergers disorder or Pervasive Developmental Disorder (PDD) not otherwise specified, established by clinical assessment and corroborated by Autism Diagnostic Interview scores
3. Patients must score greater than four on the Clinical Global Impressions (CGI)-severity scale with regard to ADHD symptoms and score at least 1.5 standard deviations above the age norm for their diagnostic subtype using published norms for the Attention-Deficit/Hyperactivity Rating Scale four (ADHDRS-IV) Parent Version
4. Outpatients
5. Medication-free for at least two weeks for all psychotropic medications (four weeks for fluoxetine or neuroleptics)
6. Intelligence Quotient (IQ) of at least 70
7. Laboratory results, including serum chemistries, hematology, and urinalysis, show no significant abnormalities and there is no clinical information that, in the judgment of a physician, should preclude a patients participation at study entry
8. Patients and parents (legal representative) have been judged by the investigator to be reliable to keep appointments for clinic visits and all tests, including venapunctures, and examinations required by the protocol. Patients must also be able to swallow capsules (study drug)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 years

Upper age limit

17 years

Sex

All

Total final enrolment

12

Key exclusion criteria

1. Patients who weigh less than 20 kg at study entry
2. Females with a positive beta-Human Chorionic Gonadotropin (HCG) pregnancy test
3. Patients with a history of severe allergies to more than one class of medications or multiple adverse drug reactions
4. DSM-IV TR diagnosis of a PDD other than Autistic Disorder, PDD- Not Otherwise Specified, Aspergers Disorder (e.g., Retts Disorder, Childhood Disintegrative Disorder), schizophrenia, another psychotic disorder, substance abuse
5. A significant medical condition such as heart disease, hypertension, liver or renal failure, pulmonary disease, or seizure disorder identified by history, physical examination, or laboratory tests

Date of first enrolment

25/02/2004

Date of final enrolment

20/10/2004

Locations**Countries of recruitment**

Netherlands

Study participating centre

University Medical Centre Groningen (UMCG)

Groningen

Netherlands

9713 GZ

Sponsor information

Organisation

Accare (The Netherlands)

ROR

<https://ror.org/02h4pw461>

Funder(s)**Funder type**

Industry

Funder Name

Eli Lilly Holdings Limited (UK)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/10/2006	26/03/2021	Yes	No