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

Submission date	Recruitment status	[_] Prospectively registered
26/02/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/02/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/03/2021	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Single-centre

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
25/02/2004

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

Age group
Child

Lower age limit
6 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
12

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)

Sponsor details
Division University Centre for Child and Adolescent Psychiatry
P.O. Box 660
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Sponsor type
Hospital/treatment centre

Website
http://www.accare.nl/

ROR
https://ror.org/02h4pw461

Funder(s)

Funder type
Industry

Funder Name
Eli Lilly Holdings Limited (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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