Atomoxetine in children with pervasive developmental disorders.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21784

Source
Nationaal Trial Register

Brief title
AAAS

Health condition

Atomoxetine treatment.

Sponsors and support

Primary sponsor: Accare, division University Center for Child and Adolescent Psychiatry, PO Box 660, 9700 AR Groningen, The Netherlands
Source(s) of monetary or material Support: Eli Lilly and Company

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

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 Children's Social Behavior Questionnaire (CSBQ);

6. Nisonger Child Behavior Rating Form;

7. Children's Yale-Brown Obsessive;

8. Compulsive Scale;

9. Child Health and Illness Profile-CE;

10. Cognitive Battery: WISC-III Mazes, WISC-III Working Memory;

11. Vineland Maladaptive Subscale;

12. Safety measures: routine lab, physical examination, EKG, open-ended questioning for adverse events.

Study description

Background summary

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

Study objective

Atomoxetine will be effective in reducing symptoms of inattention and overactivity in children and adolescents with ASD.

Study design

N/A

Intervention

Treatment with open label atomoxetine for 10 weeks.

Contacts

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Eligibility criteria

Inclusion criteria

1. Males and females between the ages of at least 6 years of age and not more than 17 years of age at visit 1;

2. ASD (DSM-IV TR diagnosis of autistic disorder or Asperger's disorder or PDD not otherwise specified, established by clinical assessment and corroborated by Autism Diagnostic Interview scores;

3. Patients must score greater than 4 on the CGI-Severity 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 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. 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 patient's 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).

Exclusion criteria

1. Patients who weigh less than 20 kg at study entry;

2. Females with a positive Beta HCG pregnancy test;

3. Patients with a history of severe allergies to more than 1 class of medications or multiple adverse drug reactions;

4. DSM-IV TR diagnosis of a PDD other than Autistic Disorder, PDD-NOS, Asperger's Disorder (e.g., Rett's 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.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-02-2004
Enrollment:	12
Type:	Actual

Ethics review

Positive opinion

Date:	12-09-2005
Application type:	First submission

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
NTR-new	NL407
NTR-old	NTR447
Other	: N/A
ISRCTN	ISRCTN25479460

Study results

Summary results

Pieter W. Troost, M.D., Mark-Peter Steenhuis, M.S., Hanneke G. Tuynman-Qua, M.D., Luuk Kalverdijk, M.D., Lawrence Scahill, M.S.N., Ph.D., Jan K. Buitelaar, M.D., Ph.D., Ruud B. Minderaa, M.D. Ph. D., Pieter J. Hoekstra, M.D., Ph. D. Atomoxetine for Attention-Deficit Hyperactivity Disorder Symptoms in Children with Pervasive Developmental Disorders: a Pilot Study. Submitted.