Atomoxetine in children with pervasive developmental disorders.

Gepubliceerd: 12-09-2005 Laatst bijgewerkt: 13-12-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21784

Bron
Nationaal Trial Register

Verkorte titel
AAAS

Aandoening

Atomoxetine treatment.

Ondersteuning

Primaire sponsor: Accare, division University Center for Child and Adolescent Psychiatry, PO Box 660, 9700 AR Groningen, The Netherlands
Overige ondersteuning: Eli Lilly and Company

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Treatment with open label atomoxetine for 10 weeks.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	25-02-2004
Aantal proefpersonen:	12
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	12-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL407
NTR-old	NTR447
Ander register	: N/A
ISRCTN	ISRCTN25479460

Resultaten

Samenvatting resultaten
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.