Risperidone in Children and Adolescents with severe disruptive behavior problems.

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Protocol I: 1. Risperidone will be effective in reducing impulsive aggression, agitation, self-injurious behavior and troublesome repetitive behavior associated with autism and related disorders; 2. Risperidone will result in sedation (...

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

Samenvatting

ID

NL-OMON23170

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

1. Patients continuing on risperidone;

2. Patients randomized to placebo.

Ondersteuning

Primaire sponsor: Accare, division University Center for Child and Adolescent Psychiatry
Hanzeplein 1,
9713 GZ Groningen,
the Netherlands
Overige ondersteuning: The Korczak Foundation for Autism and Related Disorders. Study medications were donated by Janssen Cilag BV.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Protocol I: The Irritability Scale of the Aberrant Behavior Checklist (ABC) and the Clinician’s Global Improvement score.
Protocol II: The proportion of patients in each treatment group (i.e., active, placebo) who relapse during the randomization phase.

Toelichting onderzoek

Achtergrond van het onderzoek

This study indicates the effectiveness of risperidone over a period of several months regarding reducing disruptive behavior in about half of the children with autism spectrum disorders.
The results provide a rationale for the continuing use of risperidone beyond 6 months, although considerable weight gain can limit the use of this agent.

Doel van het onderzoek

Protocol I:

1. Risperidone will be effective in reducing impulsive aggression, agitation, self-injurious behavior and troublesome repetitive behavior associated with autism and related disorders;

2. Risperidone will result in sedation (transient) and weight gain.

Protocol II:

1. Patients continued on risperidone will be significantly less likely to experience exacerbation of symptoms of irritability, aggression, agitation, and stereotypy than those randomized to placebo, as measured by the Aberrant Behavior Checklist (ABC) and the Children's Yale-Brown Obsessive Compulsive Scale (CY-BOCS).

2. Patients continued on risperidone would show superior adjustment and functioning at the end of the trial, as evidenced by lower Clinical Global Impression ratings, when compared to patients randomized to placebo.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Treament with risperidone.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age between 5 and 17 years 2 months;

2. Body weight > 15 kg;

3. DSM-IV TR diagnosis of Autistic Spectrum Disorder (Autistic disorder or Asperger syndrome or PDDNOS (established by clinical assessment, corroborated by algorithm cutoff scores on the Autism Diagnostic Interview);

4. Inpatients or outpatients;

5. Medication-free for at least two weeks for all psychotropic medications (four weeks for fluoxetine or depot neuroleptics). In the case of ADHD-comorbidity ritalin can be continued, provided that no changes in dose during the study will occur;

6. Anticonvulsants used for the treatment of a seizure disorder will be permitted if the dosage has been stable for 4 weeks and the patient is seizure free for at least 6months;

7. Clinical Global Impression (CGI) severity score of at least 4; and a score of 18 or greater on the Irritability Scale of the Aberrant Behavior Checklist;

8. A mental age of at least 18 months as measured by the age –appropriate form of the Wechsler Intelligence test (whenever possible) or by the revised Leiter or by the Mullen.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Females with a positive Beta HCG pregnancy test;

2. Evidence of hypersensitivity to risperidone (defined as allergic response [e.g., skin rash] or potentially serious adverse effect [e.g., significant tachycardia];

3. Past history of neuroleptic malignant syndrome;

4. DSM-IV TR diagnosis of a Pervasive Developmental Disorder 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 unstable seizure disorder identified by history, physical examination or laboratory tests.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind

Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	15-05-2002
Aantal proefpersonen:	36
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	09-09-2005
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	NL256
NTR-old	NTR294
Ander register	: N/A
ISRCTN	ISRCTN17120714

Resultaten

Samenvatting resultaten

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