Risperidone in Children and Adolescents with severe disruptive behavior problems.

No registrations found.

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

Summary

ID

NL-OMON23170

Source
Nationaal Trial Register

Brief title
N/A

Health condition

1. Patients continuing on risperidone;

2. Patients randomized to placebo.

Sponsors and support

Primary sponsor: Accare, division University Center for Child and Adolescent Psychiatry
Hanzeplein 1,
9713 GZ Groningen,
the Netherlands
Source(s) of monetary or material Support: The Korczak Foundation for Autism and Related Disorders.
Study medications were donated by Janssen Cilag BV.

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. CYBOCS;

2. The other subscales of the ABC;

3. Children Social Behavior Questionnaire;

4. Amsterdam Neuropsychological Tasks;

5. Adverse events as measured by a a 32-item questionnaire;

6. Simpson-Angus Scale;

7. Abnormal Involuntary Movement Scale.

Study description

Background summary

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.

Study objective

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.

Study design

N/A

Intervention

Treament with risperidone.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-05-2002
Enrollment:	36
Type:	Actual

Ethics review

Positive opinion

Date:	09-09-2005
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	NL256
NTR-old	NTR294
Other	: N/A
ISRCTN	ISRCTN17120714

Study results

Summary results

Pieter W. Troost, M.D., Bertine E. Lahuis, M.D., Mark-Peter Steenhuis, M.S., Cees E.J. Ketelaars, M.D., Ph.D., Jan K. Buitelaar, M.D., Ph.D., Herman van Engeland, M.D., Ph.D., Lawrence Scahill, M.S.N., Ph.D., Ruud B. Minderaa, M.D., Ph.D., Pieter J. Hoekstra, M.D., Ph.D. Long term effects of Risperidone in children with Autism Spectrum Disorders: A placebo discontinuation study. J Am Acad Child Adolesc Psychiatry 2005 Nov;44(11):1137-44.