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# Risperidone in children and adolescents with severe disruptive behaviour problems

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 20/12/2005 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 20/12/2005 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 14/04/2011 | 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

**Protocol serial number**
NTR294

## Study information

**Scientific Title**
Protocol I: An Open Label Study of Risperidone in Children and Adolescents with Autism and Other Pervasive Disorders.

Protocol II: An Open Label Continuation Study of Risperidone in Children and Adolescents with Autism and Other Pervasive Disorders Followed By a Double-Blind, Placebo-Controlled Discontinuation Study.

## Study objectives
Protocol I:
1. Risperidone will be effective in reducing impulsive aggression, agitation, self-injurious behaviour and troublesome repetitive behaviour 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 randomised to placebo, as measured by the Aberrant Behaviour 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 randomised to placebo

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics approval received from the local medical ethics committee

## Primary study design
Interventional

## Study design
Multicentre, randomised, double blind, placebo controlled, parallel group trial

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Psychiatric, mental disorders/illness

## Interventions
Treatment with risperidone

## Intervention Type
Drug

## Phase
Not Specified

## Drug/device/biological/vaccine name(s)
Risperidone

## Primary outcome(s)

Protocol I: the Irritability Scale of the Aberrant Behaviour Checklist (ABC) and the Clinicians Global Improvement score
Protocol II: the proportion of patients in each treatment group (i.e., active, placebo) who relapse during the randomisation phase

### Key secondary outcome(s)
1. Children's Yale-Brown Obsessive Compulsive Scale (CYBOCS)
2. The other subscales of the ABC
3. Children Social Behavior Questionnaire
4. Amsterdam Neuropsychological Tasks
5. Adverse events as measured by a 32-item questionnaire
6. Simpson-Angus Scale
7. Abnormal Involuntary Movement Scale

### Completion date
11/11/2003

## Eligibility

### Key inclusion criteria
1. Age between 5 and 17 years 2 months
2. Body weight greater than 15 kg
3. Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM-IV TR) diagnosis of Autistic Spectrum Disorder (Autistic disorder or Asperger syndrome or Pervasive Developmental Disorder, Not Otherwise Specified [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-co morbidity 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 6 months
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

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Child

### Lower age limit
5 Years

### Upper age limit

17 Years

### Sex
All

### Key exclusion criteria
1. Females with a positive Beta Human Chorionic Gonadotropin (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, 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 unstable seizure disorder identified by history, physical examination or laboratory tests

### Date of first enrolment
15/05/2002

### Date of final enrolment
11/11/2003

## Locations

### Countries of recruitment
Netherlands

### Study participating centre
**University Medical Center Groningen**
Groningen
Netherlands
9713 GZ

## Sponsor information

### Organisation
National Expertise Centre for Child and Adolescent Psychiatry (Accare) (Netherlands)

### ROR
https://ror.org/02h4pw461

## Funder(s)

**Funder type**
Industry

**Funder Name**
Janssen Cilag BV (Netherlands)

**Funder Name**
The Korczak Foundation for Autism and Related Disorders (Netherlands)

# Results and Publications

## 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 | results | 01/11/2005 | | Yes | No |
| Results article | results | 01/10/2006 | | Yes | No |
| Results article | results | 01/12/2010 | | Yes | No |