

Risperidone in children and adolescents with severe disruptive behaviour problems

Submission date
20/12/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
20/12/2005

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
14/04/2011

Condition category
Mental and Behavioural Disorders

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

Study design

Multicentre, randomised, double blind, placebo controlled, parallel group trial

Primary study design

Interventional

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