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Risperidone in children and adolescents with severe disruptive behaviour problems

Submission date	Recruitment status
20/12/2005	No longer recruiting
Registration date	**Overall study status**
20/12/2005	Completed
Last Edited	**Condition category**
14/04/2011	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
15/05/2002

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

Age group
Child

Lower age limit
5 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
36

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)

Sponsor details
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Sponsor type
University/education

Website
http://www.accare.nl/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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