

A study to investigate efficacy, safety and tolerability of a medicine (risperidone) in treatment of aggression in children and adolescents.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21876

Source

NTR

Brief title

PERS2 - CONCA

Health condition

Conduct Disorder

Children

Adolescents

Aggression

Risperidone

Efficacy

Safety

Tolerability

Agressie

Kinderen

Adolescenten

Risperidon

Medicatie

Effectiviteit

Veiligheid

Sponsors and support

Primary sponsor: Prof J.K. Buitelaar, Radboud University Medical Centre, Nijmegen, The Netherlands

Source(s) of monetary or material Support: EU FP 7

Intervention

Outcome measures

Primary outcome

The rating scales used in this study are accepted methods for assessing the respective variables for which they were developed. It is proposed that treatment with risperidone may reduce disruptive behaviour so that patients suffering from CD can function better and engage more effectively in their external environment.

The use of the ODD/CD (D-Total) composite of the Nisonger CBRF-TIQ (Aman et al., 2008) as the primary outcome measure will assess the effect of risperidone treatment on disruptive behaviour.

Secondary outcome

The secondary outcome measures focus on assessment of changes with active treatment vs. placebo:

1. CGI-I and CGI-S (Guy 1976; NIMH 1985);
2. C-GAS (Shaffer et al., 1983);
3. ADHD-DSM IV_RS (DuPaul et al., 1998);
4. OAS (Yudofsky et al., 1986);
5. CHIP-CE (Riley et al., 2004);
6. Child Behavior Checklist (CBCL), parent-reported (Achenbach, 1991a);
7. PAERS (March et al., 2007) (The PAERS will be used to evaluate AEs in a standardized approach (March et al., 2007);
8. ANT subtests (de Sonnevile, 1999);
9. Columbia SSR (Posner et al., 2007b);
10. Additional outcomes related to Informed Consent procedures, Treatment Compliance,

etc., potential mediators and moderators for efficacy and tolerability/safety parameters.

Previous placebo-controlled studies in children and adolescents with CD with risperidone have shown that patients treated with risperidone manifested increases in body weight compared with placebo (Reyes et al. 2006a, Shea et al. 2004). Therefore it is appropriate to monitor patients' weight and BMI throughout the study.

In addition, it is also appropriate for patients taking second-generation antipsychotics such as risperidone to have, e.g., their fasting lipid profile, fasting glucose, blood pressure, and prolactin monitored.

Study description

Background summary

The current study will focus on investigating short-term (acute) efficacy and safety/tolerability of risperidone in the treatment of paediatric patients, children and adolescents, with DSM-IV-TR conduct disorder and normal intelligence (or higher), on a patient population in which this compound has not systematically been studied, but has regularly been used to a large extent in clinical routine in child and adolescent psychiatry and/or paediatrics (Kalverdijk et al., 2008, Olfson et al. 2006, Rani et al., 2008,).

Study will be conducted in: The Netherlands, Belgium, Germany, United Kingdom, France, Spain, Italy.

Study objective

The primary objective of this study is to test the hypothesis that risperidone given orally in a dose of 0.25 – 3.0 mg/d depending on body weight (eq. to approximately 0.01 – 0.04 mg/kg/d) for 12 weeks is superior to placebo in reducing disruptive behavioural symptoms associated with DSM-IV-TR defined Conduct Disorder (CD) in the treatment of in- and outpatient children and adolescents not mentally retarded.

To test the hypothesis that risperidone is superior to placebo in reducing disruptive behaviours associated with CD over 12 weeks of double-blind treatment.

To test the hypothesis that risperidone is superior to placebo in improving functional outcomes over 12 weeks of double-blind treatment.

To test the effect of risperidone compared to placebo on various other behavioural domains over 12 weeks of double-blind treatment.

To assess the effect of risperidone compared to placebo on comorbid ADHD symptoms over 12 weeks of double-blind treatment.

To assess the effect of risperidone compared to placebo on (impairment of) cognition/cognitive functioning (e.g. due to possible sedative effects) over 12 weeks of double-blind treatment using the following assessment, a cognitive battery including attentional and set-shifting tests.

To compare safety and tolerability results for risperidone and placebo in children and adolescents with CD over 12 weeks of double-blind treatment.

Study design

Over a period of 12 weeks, measurements will be conducted weekly and later bi-weekly.

Intervention

Participants will receive either the risperidone or the placebo tablets for the duration of 12 weeks.

Drug 1: These tablets contain 0.25 mg, 0.5 mg or 1.0 mg of Risperidone. The maximum daily dose in this study is 3.0 mg;

Drug 2: These tablets contain a so-called placebo. Placebos look like drug 1, but don't contain any medically active components.

Contacts

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Eligibility criteria

Inclusion criteria

Patients are eligible to be included in the study only if they meet all of the inclusion criteria below:

1. Male or female patients aged 5.0 - <17.0 years at Visit 1;
2. Patients must have an IQ of > 85 (based on, e.g., 4 WISC subtests): vocabulary, similarities, block design, and matrix reasoning (cf. Crawford et al., 2010. Age- and country-specific adaptations will be used;
3. Patients must meet DSM-IV-TR diagnostic criteria for DSM-IV-TR Conduct Disorder(s) as confirmed by the Kiddie-SADS, Conduct Disorder Module: 312.8x. (Kaufman et al., 1996), at Visit 2 or Visit 3;
4. Patients must score ≥ 27 on the Nisonger CBR Form, ODD/CD Disruptive Behavior Composite (D-Total) either at Visit 2 or Visit 3;
5. Patients must score ≥ 4 (\geq moderately ill; \geq (or > 5 , \geq markedly ill; \geq) on the CGI-S rating scale at Visits 2 and 3;
6. If a female of child-bearing potential, patients must test negative for pregnancy at the time of enrollment based on a serum pregnancy test and agree to use a reliable method of birth control. (Adequate contraception includes: oral contraceptives, intrauterine devices; double barrier method (diaphragm or condom plus spermicide), Norplant® or Depot Provera®);
7. Patients must have a body weight of at least 20 kg at study entry;
8. Patients must be able to swallow study drug;
9. Patients must have venous access sufficient to allow blood sampling and are compliant with blood draws as per protocol;

10. Subjects; – parents/legal guardians must provide and sign informed consent documents; Patients must provide informed consent, and sign consent or assent documents if capable, according to the legal requirements in the very country;
11. A reliable person (primary caregiver, parent) must be available to ensure compliance with study procedures throughout the course of the study;
12. Patients meeting criteria for comorbid ADHD (as to the clinical judgment of the investigator) will not be excluded from study participation.

Exclusion criteria

A patient will be excluded from the study if he or she meets any exclusion criteria described below, according to the assessment of the investigator:

1. Is immediate family of investigator site personnel directly affiliated with this study. Immediate family is defined as a spouse, parent, child, or sibling, whether biological or legally adopted;
2. Has been treated with a drug within 14 days before Visit 1 that has not received regulatory approval for any indication at the time of study entry;
3. Has participated in any investigational drug trial within six months prior to baseline (visit 3);
4. Has previously completed or withdrawn from this study or any other study investigating risperidone or has previously been identified as being a nonresponder or intolerant of risperidone;
5. Has a current (within 6 months of the start of the study) or lifetime DSM-IV-TR diagnosis of schizophrenia-related disorders, schizophrenia, bipolar disorder, major depressive disorder, or current substance dependence disorder (given the nature of the study population substance misuse or abuse is not exclusionary), pervasive developmental disorder (autistic disorder or Asperger disorder);
6. In the clinical judgment of the investigator, meets criteria for a primary psychiatric disorder, e.g., Anxiety Disorder, Depressive Disorder, Tic Disorder or Tourette's Syndrome (comorbid ADHD is permitted, cf. Incl. criteria section);
7. Starts any psychotropic medication, including health-food supplements that the investigator feels could have central nervous system activity (for example, St. John's Wort, melatonin), during the course of the study, or is taking any other excluded concomitant medication(s) at/beyond Visit 2 (specified in Section 5.7). (An ongoing long-term medication, e.g., to treat a comorbid disorder such as ADHD, is permitted as long as compound and dose are not changed throughout the course of the study.);

8. Has any acute or unstable medical condition, physiological condition, clinically significant laboratory, or ECG results that, in the opinion of the investigator, would compromise participation in the study;
9. Has a known or suspected seizure disorder;
10. Has a history of neuroleptic malignant syndrome (NMS) or of tardive dyskinesia;
11. Has a history of hypersensitivity to neuroleptics, of tardive dyskinesia, or neuroleptic malignant syndrome;
12. Is pregnant or nursing.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-04-2012
Enrollment:	264
Type:	Anticipated

Ethics review

Not applicable	
Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 38186

Bron: ToetsingOnline

Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3070
NTR-old	NTR3218
CCMO	NL35625.091.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38186

Study results

Summary results

N/A