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

Gepubliceerd: 29-12-2011 Laatst bijgewerkt: 15-05-2024

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21876

Bron
NTR

Verkorte titel
PERS2 - CONCA

Aandoening

Conduct Disorder
Children
Adolescents
Aggression
Risperidone
Efficacy
Safety
Tolerability

Agressie
Kinderen
Adolescenten
Risperidon

Medicatie
Effectiviteit
Veiligheid

Ondersteuning

Primaire sponsor: Prof J.K. Buitelaar, Radboud University Medical Centre, Nijmegen, The Netherlands
Overige ondersteuning: EU FP 7

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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 ¡Ã 27 on the Nisonger CBR Form, ODD/CD Disruptive Behavior Composite (D-Total) either at Visit 2 or Visit 3;

5. Patients must score ¡Ã4 (¡°moderately ill¡± (or > 5, ¡°markedly ill¡±) 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 contra- ception includes: oral contraceptives, intraueterine devices; double barrier method (diaphragm or condom plus spermicide), Norplant¢â or Depot Provera¢â));

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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 exlusionary), 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2012
Aantal proefpersonen:	264
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 38186
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A