Off-label use of Risperidone in Children and Adolescents (ORCA): a double-blind placebo-controlled discontinuation trial

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20175

Source
Nationaal Trial Register

Brief title
ORKA

Health condition

Risperidone, long-term efficacy and safety, risperidon, langetermijn effectiviteit

Sponsors and support

Primary sponsor: University Medical Center Groningen (UMCG)
Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

The primary outcome measure will be the D-total score of the Nisonger Child Behavior Rating Form-Typical IQ (NCBRF-TIQ).

Secondary outcome

- Strength and Difficulties Questionnaire (SDQ)

- Retrospective Modified Overt Aggression Scale (R-MOAS)

- Conners Teacher Rating Scale-Revised: short form (CTRS-R:S)

- Clinical Global Impression Scale (CGI)

- Children's Global Assessment Scale (CGAS)

- Kindl-R (quality of life)

- Parental Frustration Questionnaire (PFQ)

- Amsterdam Neuropsychological Tasks (ANT)

- UKU side effect rating scale (UKU-SERS)

- Abnormal Involuntary Movement Scale (AIMS)

- Barnes Akathisia Scale (BARS)

- Unified Parkinson's disease rating scale (UPDRS)

- Sleep Disturbances Scale for Children (SDSC)

- appetite and life style - Physical Activity Questionnaire (PAQ)

- Physical measures: length, weight, waist circumference, heart rate and blood pressure

- Blood counts

• Metabolism: fasting glucose, insulin, triglycerides, high-density lipoproteins (HDL), low-density lipoproteins (LDL), leptine, and total cholesterol.

• Endocrine parameters: prolactin, testosterone, and estradiol.

• Thyroid function: TSH, T4, and parathyreoid hormone.

• Kidney function: creatinine, sodium, and potassium.
• Pharmacokinetics: risperidone and 9-hydroxyrisperidone concentrations.

• Albumine levels. Predictor variables:

- Demographic data and socio-economic status

- Treatment history and psychiatric diagnosis

- Tanner stages of pubertal development

- Parent-rating scale for Reactive and Proactive Aggression (PRPA)

- Nijmeegse OUderlijke Stress Index - kort (NOSI-K)

- Alabama Parenting Questionnaire (APQ)

Study description

Background summary

The ORCA study is a multicenter, double blind, placebo-controlled discontinuation trial in which 120 children and adolescents (6 to 17;8 years, IQ> 70) who have been using risperidone for over a year, will at random either gradually discontinue to placebo or continue their use. Discontinuation will be done in an 8-week period, after which participants will use only placebo for 8 weeks. Measurements will take place at baseline, 8 weeks and 14 weeks after baseline and after 6 months (naturalistic).
The aim is to determine whether long-term use of risperidone after at least a year is still effective, to determine the effects of discontinuing on behavior and physical health and the feasibility of stopping this treatment.

Study objective

We will test the hypothesis that ongoing use of risperidone is superior to placebo with regard to behavioral symptoms in children and adolescents who have used risperidone for a year or longer.

Study design

Baseline

8-week follow-up

14 week follow-up and immediate breaking of the blind

Naturalistic follow-up after 6 months

Intervention

The participating subjects will be randomized (ratio 1:1) to either continued use of risperidone or to placebo during sixteen weeks. After two weeks of accommodating to the study medication, withdrawal will be gradual over a period of six weeks, followed by eight weeks of complete placebo. There will be four visits, at the start of the study, at baseline and after eight and fourteen weeks after baseline. After six months there will be a follow up by telephone.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Be between the ages of six and seventeen years and eight months

- Current risperidone use ≥ one year.

- Current risperidone doses ≤ 5 mg/day.

- IQ > 70 (based on a previous IQ test or attending regular education).

- Parents (or the legal guardian) and children (≥ twelve years) have provided informed consent to participate in the study.

Exclusion criteria

- Risperidone was discontinued for ≥ two months in the last year.

- Current psychosis.

- Pregnancy.

- Risperidone is primarily used for the treatment of psychosis or tics.

- Having parents who are planning to start other psychosocial and pharmacological therapies during the blinded period.

- Having parents who are unable to understand or comply with the protocol.

- Presence of any other significant disease or disorder which, in the opinion of the investigator, may either put the participants at risk because of participation in the study, or may influence the results of the study, or the participant's ability to participate in the study.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-01-2016
Enrollment:	120

Type:	Anticipated

Ethics review

Positive opinion

Date:	16-12-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44901
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5451
NTR-old	NTR5595
CCMO	NL52899.042.15
OMON	NL-OMON44901

Study results