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

Gepubliceerd: 16-12-2015 Laatst bijgewerkt: 19-03-2025

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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20175

Bron
Nationaal Trial Register

Verkorte titel
ORKA

Aandoening

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

Ondersteuning

Primaire sponsor: University Medical Center Groningen (UMCG)
Overige ondersteuning: ZON-MW, The Netherlands Organization for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Baseline

8-week follow-up

14 week follow-up and immediate breaking of the blind

Naturalistic follow-up after 6 months

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	04-01-2016
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	16-12-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44901
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten