Safety and pharmacokinetics of antipsychotics in children 2: Studying TDM in an RCT

Gepubliceerd: 21-10-2021 Laatst bijgewerkt: 18-08-2022

We hypothesize that therapeutic drug monitoring of risperidone in children with an autism spectrum disorder and comorbid behavioral problems will reduce metabolic side effect burden, while retaining clinical effectiveness.

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

Samenvatting

ID

NL-OMON23089

Bron
NTR

Verkorte titel
SPACe 2: STAR

Aandoening

Autism Spectrum Disorder

Ondersteuning

Primaire sponsor: Erasmus Medical Center Rotterdam
Overige ondersteuning: Erasmus MC, Stichting de Merel, ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Difference in body mass index z-scores 6 months after start of treatment.

Toelichting onderzoek

Achtergrond van het onderzoek

Main objective:
Our goal is to study the effectivity of therapeutic drug monitoring to prevent or mitigate side effects of risperidone use in children and adolescents. To this end we will study the differences in weight gain six months after start of treatment with risperidone between a group of children receiving therapeutic drug monitoring based dosing advice and a group of children receiving risperidone according to standard clinical care.

Secondary Objectives:
For our secondary objectives we will compare drug effectivity between the groups, based on severity of irritability and aggression as measured by the Aberrant Behavior Checklist (ABC). The following secondary safety parameters will be compared between the groups: levels of glucose, cholesterol, lipoproteins and triglycerides; the hormones ghrelin, prolactin and leptin as well the level of extrapyramidal side effects as measured by the Abnormal Involuntary Movement Scale (AIMS).

Doel van het onderzoek

We hypothesize that therapeutic drug monitoring of risperidone in children with an autism spectrum disorder and comorbid behavioral problems will reduce metabolic side effect burden, while retaining clinical effectiveness.

Onderzoeksopzet

Start, 4 weeks, 10 weeks, 24 weeks

Onderzoeksproduct en/of interventie

Therapeutic drug monitoring: dosing advice of risperidone based on measured blood concentration of risperidone and 9-OH-risperidone.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Age 6 to 18 years
• Documented clinical diagnosis of autism spectrum disorder according to DSM IV or DSM V and comorbid behavioural problems
• To start treatment with risperidone

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Diabetes type I or II
• Congenital or acquired syndrome associated with changes in appetite, body weight or lipid profile (e.g. Prader Willi)
• Treatment with antipsychotic medication within the last 6 months
• Known Long QT syndrome (LQTS)
• Pregnancy

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2021
Aantal proefpersonen:	140
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	21-10-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9824

Register	ID
Ander register	METC Erasmus MC : MEC-2021-0278

Resultaten