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

No registrations found.

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

Summary

ID

NL-OMON23089

Source
NTR

Brief title
SPACe 2: STAR

Health condition

Autism Spectrum Disorder

Sponsors and support

Primary sponsor: Erasmus Medical Center Rotterdam
Source(s) of monetary or material Support: Erasmus MC, Stichting de Merel, ZonMw

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Effectivity, measured using the Aberrant Behavior Checklist (ABC). Secondary safety parameters: Levels of glucose, cholesterol, lipoproteins and triglycerides; the hormones ghrelin, prolactin and leptin. Abnormal Involuntary Movement Scale (AIMS), a clinician administered observational scale aimed at detecting extrapyramidal side effects.

Study description

Background summary

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).

Study objective

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.

Study design

Start, 4 weeks, 10 weeks, 24 weeks

Intervention

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

Contacts

Public
Erasmus MC
Rebecca Hermans

06 500 318 13
Scientific
Erasmus MC
Rebecca Hermans

06 500 318 13

Eligibility criteria

Inclusion criteria

• 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

Exclusion criteria

• 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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2021
Enrollment:	140
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	21-10-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9824
Other	METC Erasmus MC : MEC-2021-0278

Study results