Safety and pharmacokinetics of antipsychotics in children with autism

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22814

Source
Nationaal Trial Register

Brief title
SPACe

Health condition

Autism Spectrum Disorder (autisme spectrum stoornis)

Sponsors and support

Primary sponsor: Erasmus Medical Center Rotterdam
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

First, a pharmacokinetic (PK) model is built, linking dosage to drug plasma levels.

Second, in the pharmacodynamic (PD) analysis we will investigate the relation between the pharmacokinetic model and weight change.

Secondary outcome

In a second pharmacodynamic (PD) analysis we will investigate the relation between the pharmacokinetic model and cardiac
changes, extrapyramidal symptoms, metabolic abnormalities, somnolence and clinical effectiveness.

We will also verify the relationship between DBS and venipuncture measurements of drug plasma levels in a small subgroup of children.

Study description

Background summary

Our main objective is to develop a pharmacokinetic safety window in children and adolescents for the three most prescribed antipsychotics in the Netherlands, risperidone, pipamperon and aripiprazole. To this end we will study the relation of the measured pharmacokinetic parameters with weight change and extrapyramidal side effects over a 6 month period using a minimally invasive Dry Blood Spot technique (DBS).

As a secondary objective, we will investigate the relation between the plasma levels of the antipsychotics and cardiac changes, metabolic abnormalities, somnolence and clinical effectiveness. We will conduct a multicentre, prospective, observational cohort study. No study intervention will occur. We will include 30 patients in each treatment group which will be followed for 6 months.

Study objective

The occurrence of clinical side effects in children using aripiprazole, risperidone or pipamperone can be modeled using drug plasma levels.

Study design

Start, 4 weeks, 12 weeks, 24 weeks

Intervention

None

Contacts

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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 either aripiprazole, risperidone or pipamperone

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)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2016
Enrollment:	90
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	05-08-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47545
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5879
NTR-old	NTR6050
CCMO	NL56247.078.16
OMON	NL-OMON47545

Study results