Clinical validation of the Dry Blood Spot (DBS) method for risperidone, aripiprazole, pipamperone and its major metabolites

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the clinical validation of the DBS method for determination of risperidone, pipamperon and aripiprazole and their metabolites.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Disturbances in thinking and perception
Study type	Observational invasive

Summary

ID

NL-OMON45799

Source
ToetsingOnline

Brief title
DAPpeR: Dried blood spot of Aripiprazole, Pipamperone, Risperidone

Condition

- Disturbances in thinking and perception

Synonym
nvt

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Antipsychotics, Aripiprazole, Dried Blood Spot, Pipamperone, Risperidone, Therapeutic Drug Monitoring

Outcome measures

Primary outcome

the main study parameter is the agreement between antipsychotic drug plasma

levels of blood collected by venipuncture or DBS, both measured by

ultra-performance liquid chromatography tandem mass-spectrometry (UHPLC-MS/MS)

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Secondary outcome

Covariates influencing through levels

Study description

Background summary

Antipsychotic drugs play an important role in the treatment of comorbid behavioural problems in children with autism spectrum disorders (ASD). Unfortunately, treatment with anti-psychotics is associated with a number of serious side effects, like cardiac, metabolic and extrapyramidal abnormalities. Therapeutic Drug Monitoring (TDM) could help to achieve the best therapeutic results with the lower risk of toxicity and side effects. The advan¬tages in of the new Dry Blood Spot (DBS) method have been recognized for use in TDM. DBS allows drug monitoring in a home setting with a single fingerprick, which is less invasive, painful and stressful. A DBS method for determination of the mostly prescribed antipsychotics risperidone, pipamperone and aripiprazole

Study objective

the clinical validation of the DBS method for determination of risperidone, pipamperon and aripiprazole and their metabolites.

Study design

cross-sectional intervention study

Study burden and risks

Participants will undergo one fingerprick, which will cause mild local irritation. Possibly an extra blood sample will be taken during regular, scheduled venipuncture, which will cause no extra inconvenience. If no venipuncture was planned, a venipuncture will be done which might cause mild local pain. The procedures only take 10 minutes.
Once validated DBS can be of great benefit to an extended population, as antipsychotics are commonly prescribed in the Netherlands. The associated risks of the use of this medication could be minimalized in a minimally invasive order in the home setting.
In order to reach the target study sample, also mentally disabled/incompetent persons will be included, as pipamperone is preferably and almost exclusively prescribed to this patient group.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- using either aripiprazole, risperidone, paliperidone or pipamperone
- 18 years or older

Exclusion criteria

nvt

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-06-2016
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	17-05-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	26-07-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-09-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-02-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-03-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL57233.078.16