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

No registrations found.

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

Summary

ID

NL-OMON28955

Source
Nationaal Trial Register

Brief title
DAPpeR

Health condition

antipsychotics, pipamperone, aripiprazole, paliperidone, risperidone

Sponsors and support

Primary sponsor: Erasmus MC Medical Center
Source(s) of monetary or material Support: Zon MW

Intervention

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)

Secondary outcome

Covariates influencing through levels

Study description

Background summary

The advantages 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 has been developed. The objective of this study is to clinically validate this method. 20 patients per drug will undergo a DBS fingerprick and venipuncture simultaneously. The two measurements will be compared using Deming regression and Bland Altmand plots.

Study objective

Dried Blood Spot is a reliable method to determine antipsychotic blood levels.

Study design

only one measurement

Intervention

Participants will undergo one fingerprick and venipuncture which will cause mild local irritation.

Contacts

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Eligibility criteria

Inclusion criteria

- using either aripiprazole, risperidone, paliperidone or pipamperone

- ≥ 18 years

Exclusion criteria

none

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	09-06-2016
Enrollment:	60
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date:	29-08-2017
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	NL6339
NTR-old	NTR6655
Other	METC van het Erasmus MC / toetsingonline (CCMO) : MEC-2016-123 / NL57233.078.16

Study results

Summary results
none