The influence of antipsychotic medication on dopamine D2 receptor availability. A [11C] raclopride PET study

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Schizophrenia and other psychotic disorders
Study type	Observational invasive

Summary

ID

NL-OMON55703

Source
ToetsingOnline

Brief title
Hamlett PET-study

Condition

- Schizophrenia and other psychotic disorders

Synonym
dopamine, psychosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: NWO TOP;nr 8480411003

Intervention

Keyword: dopamine, MRI, psychosis, raclopride

Outcome measures

Primary outcome

The main study parameter is be the binding potential of [11C]raclopride in the

striatum (caudate and putamen).

Secondary outcome

n.a.

Study description

Background summary

Discontinuation of antipsychotic medication after use of these drugs for several months may render patients especially vulnerable to relapse. Potential mechanism behind this vulnerability could be increased density of postsynaptic dopamine D2 receptors in the striatum. This mechanism has been demonstrated in rats and mice, but never in first episode psychosis (FEP) patients.

Study objective

The aim of the proposed study is to investigate the presence of dopaminergic abnormalities, as measured with [11C]raclopride, in relation to antipsychotic medication discontinuation in patients remitted after a first-episode psychosis (FEP). Secondary objectives are to compare baseline levels of [11C]raclopride between FEP patients in remission who have discontinued antipsychotic medication with ultra-high risk (UHR) individuals who are antipsychotic-naïve and healthy individuals who are antipsychotic-naïve.

Study design

The proposed study has an observational design. For this study, subjects will be scanned in a PET-scanner under resting conditions.

Study burden and risks

The subjects of this study will undergo a [11C]raclopride PET scan. Healthy control subjects will undergo the PET scan once. The FEP patients will undergo two PET scans, one 1-7 days after discontinuation of antipsychotic medicine and one after 6-8 weeks after discontinuation. Participation in the study will entail a session that will involve a PET scan of approximately 60 minutes. The only adverse event can be a bruise as a result of the arterial catheter. In addition, according to ICRP62 the radiation level of 2.8 mSv is within the category IIb, minor to moderate risk (1-10 mSv). For anatomical reference, which is lacking in PET, an MRI scan of the subjects is needed. For all subjects, an MRI scan will be made in addition to the PET scan. The MRI scan will last 60 minutes, and will pose no risk. The risks associated with participation and the benefits to the individuals are negligible. The potential benefit to society in the future is considerable if the findings lead to more insight in antipsychotic induced psychosis.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

* The participant understands the study and is able to provide written informed consent
* Must be between the ages of 18-60
* Sufficient command of the Dutch language
* Must have a diagnosis of schizophrenia, schizoaffective disorder, schizophreniform disorder, or those classified as Other Specified Schizophrenia Spectrum and Other Psychotic Disorder
* Be mentally competent, as determined by their treating physician
* The participant has had a first episode of psychosis and uses antipsychotic medication at the start of the HAMLETT study
* The participant is about to discontinue antipsychotic medication
* Psychotic symptoms are in remission for 3-6 months
* HAMLETT is the only medical-scientific medication study in which the patient participates

Exclusion criteria

* Presence of a neurological disorder
* Visual or hearing problems that cannot be corrected
* Participation in a scientific research study during the past year involving radiation
* the refusal to be informed (by notifying the participant*s physician) of structural brain abnormalities that could be detected during the experiment
* MR incompatible implants in the body
* Risk of having metal particles in the eyes
* Tattoo*s containing red pigments that form a safety risk
* Alcohol or substance abuse in the past 6 months
* Insufficient knowledge of the Dutch language
* Inability to undergo cognitive testing
* Use of antipsychotic medication
* dangerous or harmful behaviour (i.e. behaviour with a risk of severe physical injury, or actual physical injury inflicted, to self or others) occurred during the psychosis
* Coercive treatment (based on a judicial ruling)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-01-2019
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO Date:	30-04-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	11-12-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-06-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	30-12-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL64040.042.17