Measuring neuromelanin using MRI

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational non invasive

Summary

ID

NL-OMON45255

Source
ToetsingOnline

Brief title
Measuring neuromelanin using MRI

Condition

- Movement disorders (incl parkinsonism)
- Schizophrenia and other psychotic disorders

Synonym
Parkinson's disease, pscyhosis, schizophrenia

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: MRI, neuromelanin, Parkinson, schizophrenia

Outcome measures

Primary outcome

The difference between patients and healthy controls in neuromelanin concentration (or indirect quantitative measure or this) in the substantia nigra and locus coeruleus.

Secondary outcome

Correlations between neuromelanin concentrations (or indirect quantitative measure or this) in the substantia nigra or locus coeruleus and therapy resistance or side effects of therapy (such as extrapyramidal symptoms).

Study description

Background summary

Recently a new MRI sequence was developed, which enables us to visualized and quantify neuromelanin in the substantia nigra and locus coeruleus. The substantia nigra and locus coeruleus are core regions of, respectively, the dopaminergic and noradrenergic system. Dopamine synthesis and release are increased in schizophrenia, whereas in Parkinson's disease there is degeneration of dopaminergic neurons in the substantia nigra and noradrenergic neurons in the locus coeruleus. The first results of the new MRI sequence indeed suggest that neuromelanin concentration in the substantia nigra is increase in schizophrenia and decreased in Parkinson's disease.
The new MRI sequence provides a new opportunity to study the dopamine system and to potentially apply it for clinical use to support the clinical diagnosis of Parkinson's disease or to predict therapy resistance or extrapyramidal side-effects by antipsychotics in schizophrenia, in a non-invasie way and without radiation exposure.

Study objective

The goal of this study is to collect pilot data using the neuromelanin sensitive MRI sequence in patients with schizophrenia of psychoses, patients with Parkinson's disease and healthy controls. These pilot data will be used for grant applications for research projects assessing the clinical

applicability of this MRI sequence in schizophrenia and Parkinson's disease.

Study design

Observational
The pilot data will be used primarily to study differences between patients and healthy controls. Secondarily, we will assess whether the data shows a correlation with clinical parameters, such as therapy resistance or extrapyramidal symptoms. The data will also be used for statistical power analyses for future studies.

Study burden and risks

Because the participants will get an MRI scan for scientific research or diagnostics, the increase of scantime by 10-15 minutes has no additional risks for the participants.
It means for the participants that they will lie in the MRI scanner for 10-15 more minutes. Before start of the additional MRI sequence, they can tell whether they are still comfortable and whether they still agree to lie 10-15 more minutes in the MRI scanner.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with schizofrenia/psycosis:
* clinical diagnosis schizophrenia or schizophreniphorm disorder or psychotic episode;Patients with Parkinson's disease
* clinical diagnosis Parkinson's disease, strong indication of Parkinson's disease or Parkinsonian symptoms;Healthy controls:
* age- and gender matched with patients at group level;All participants:
* Capacity to understand the study and to sign *informed consent*.

Exclusion criteria

Healthy controls:
* Severe neurologic and psychiatric disorders
* Use of psychotropic drugs or drugs of abuse that may influence the dopamine system;All participants:
- contra-indications for MRI (including pacemaker, ferromagnetic implants, possibility of iron splinters in the orbita, claustrophobia)
- pregnancy

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO Date:	14-02-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL58706.018.16