Diagnostic accuracy of MRI for neurodegenerative parkinsonism

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The primary objective is to determine the diagnostic accuracy of the automated diagnostic software (mPDia, Heuron) using SMWI to distinguish neurodegenerative parkinsonism from patients with non-neurodegenerative parkinsonism compared with the final...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational non invasive

Summary

ID

NL-OMON54005

Source
ToetsingOnline

Brief title
MRPARK

Condition

- Movement disorders (incl parkinsonism)

Synonym
idiopathic parkinson's disease, neurodegenerative parkinsonism, Parkinson□s disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Heuron

Intervention

Keyword: DAT SPECT, magnetic resonance imaging, MRI, parkinsonism, Parkinson's disease, QSM, SMWI, Susceptibility map-weighted imaging

Outcome measures

Primary outcome

The diagnostic accuracy of the automated diagnostic software (mPDia, Heuron)

using SMWI, compared with the final diagnosis of the neurologist.

Secondary outcome

- Contrast ratio and size of the SN and LC on nmMRI

- Iron content of SN and basal ganglia on SWI using QSM

- T1 and T2 relaxation in different brain regions using MR STAT

- Free-water present in the SN on DTI

- Architecture of white matter tracts on DTI

- Contrast ratio and size of the SN on nmSMWI

- Hoehn & Yahr stage

- MDS UPDRS that consists of the following four parts will be filmed:

I. Non-motor experiences of daily living (6 items)

II. Motor experiences of daily living (20 items)

III. Motor examination (33 items)

IV. Motor complications (6 items)

- Red flags on the MDS criteria for the diagnosis of PD3

- Montreal cognitive assessment (MoCA)

- REM sleeping behavior disorder screening

- Non-motor symptom assessment scale

- Beck Depression inventory (BDI)

- Environmental factors

- Sebum swap

Study description

Background summary

The pathophysiology of Parkinson*s disease (PD) is characterized by an extensive and progressive loss of dopaminergic neurons of the substantia nigra (SN). Usually, it can be well diagnosed based on its clinical symptoms. However, particularly in the early stages of the disease, not all symptoms might be present and the diagnosis remains challenging. Recently, novel MRI sequences have been developed to assess the SN. More specific, susceptibility map weighted image (SMWI) is capable of visualizing nigrosome 1 and iron deposition in the SN. These measures are altered in nigrostriatal neurodegeneration and therefore have the potential to benefit the diagnostic process in parkinsonian patients in which the diagnosis remains unclear. Recently, an automated diagnostic algorithm that utilizes this MRI sequence showed a high potential to support the diagnosis of Parkinson*s disease within a small group of patients with a clear clinical diagnosis. It is clinically relevant yet unclear, how this technique performs in patients with an uncertain clinical diagnosis.
In recent years more promising diagnostic techniques for neurodegenerative parkinsonism have been developed. MRI sequences such as neuromelanin sensitive MRI (nmMRI), quantitative susceptibility mapping (QSM), diffusion tensor imaging (DTI) and MR STAT are capable to assess differences in the SN between patients with PD and healthy controls. In addition, recent research has shown a difference in composition of sebum in patients with PD compared with healthy controls. However, these novel techniques are not yet applied in medical practice and diagnostic accuracy has to been further investigated.

Study objective

The primary objective is to determine the diagnostic accuracy of the automated diagnostic software (mPDia, Heuron) using SMWI to distinguish neurodegenerative parkinsonism from patients with non-neurodegenerative parkinsonism compared with the final diagnosis of a neurologist including the results of DAT SPECT imaging. Secondary objectives are more exploratory to investigate the diagnostic characteristics and accuracy of nmMRI, QSM, MR STAT, DTI, and composition of sebum for neurodegenerative parkinsonism.

Study design

Combined retrospective and prospective diagnostic study.

Study burden and risks

The study does not provide a direct benefit for the participants. However, the aim of this study is to assess the diagnostic accuracy of MRI for patients with CUPS. MRI does not expose patients to radiation and is more widely available. Hence, this study benefit patients with CUPS as a group. There is no known risk of harm of the procedures of this study. Therefore, disadvantage of participation is limited.

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

- Age above 18
- DAT-SPECT scan between January 2019 and December 2021 for clinical uncertain parkisonian
syndrom

Exclusion criteria

- Indication for the DAT-SPECT other than CUPS
- Inability to provide informed consent
- Aboslute contra indication for MRI

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:	Recruiting
Start date (anticipated):	23-05-2022
Enrollment:	180
Type:	Actual

Medical products/devices used

Generic name:	mPDia;automated diagnostic software using MRI
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-01-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-04-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl
Approved WMO Date:	23-10-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

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	NL79240.018.22