PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Brain Magnetic Resonance Imaging at 3.0 Tesla in neurodegenerative parkinsonism – a pilot study

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Parkinson’s disease (PD) is the second most prevalent neurodegenerative disease after Alzheimer’s disease and the most common cause of parkinsonism. In regional brain structures there is a lack of dopamine, a neurotransmitter which is important for coordination and control of our movements. The major symptoms are tremor, slowing down of movements, rigidity and problems with gait and stability. Beside Idiopathic Parkinson’s disease (IPD) there are atypical parkinsonian disorders such as Progressive Supranuclear Palsy (PSP) and Multiple System Atrophy (MSA). Since the early eighties, magnetic resonance imaging (MRI) at 1.5 Tesla (T, unit of magnetic field) has been established in the routine diagnostic work-up of neurological disorders. In the last years high-field magnetic resonance imaging at 3.0 Tesla has rapidly gained acceptance in the MR community for both research and clinical applications. There is however a lack on studies using MRI at 3.0T for differential diagnosis of neurodegenerative parkinsonism. The aim of this study is to assess the use of MRI at 3.0T versus 1.5T for the differential diagnosis of neurodegenerative parkinsonian disorders. Therefore, patients with the clinical diagnosis of neurodegenerative parkinsonism and healthy controls will be prospectively recruited in this study. A neurological examination, an olfactory testing and two MRI analyses at 1.5T and 3.0T are going to be performed. Afterwards, an experienced independent rater will evaluate the MRI scans and statistical analysis will be used for group comparisons.

Brief Summary in Scientific Language

The differential diagnosis of neurodegenerative parkinsonian disorders including Parkinson disease (PD), progressive supranuclear palsy (PSP) and multiple system atrophy (MSA) still remains one of the most challenging in neurology. Despite published consensus operational criteria for the diagnosis of the various neurodegenerative parkinsonian disorders, differentiation of these clinical entities carries a high rate of misdiagnosis. MRI at 1.5T has been extensively studied in neurodegenerative parkinsonism and may be an useful tool in the diagnostic work-up of clinical parkinsonism. Although high-field MRI at 3.0T has gained acceptance in the MR community for both research and clinical applications in the last few years, there is a lack on studies using MRI at 3.0T for differentiation of

neurodegenerative parkinsonism. Aim of the study: To assess the use of MRI at 3.0T for differential diagnosis of neurodegenerative parkinsonian disorders including PD, MSA and PSP.

Organizational Data

- DRKS-ID: **DRKS00003299**
- Date of Registration in DRKS: **2011/10/14**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **UN4104 292/4.18 , Ethikkommission der Medizinischen Universität Innsbruck**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1125-1571**

Health condition or Problem studied

- ICD10: **G20 - Parkinson's disease**
- ICD10: **G23.1 - Progressive supranuclear ophthalmoplegia [Steele-Richardson-Olszewski]**
- ICD10: **G90.3 - Multi-system degeneration**

Interventions/Observational Groups

- Arm 1: <style fontName='DejaVu Sans' isBold='true'>Patients with clinical diagnosis of neurodegenerative parkinsonian disorder: clinical examination (UPDRS, Hoehn & Yahr), olfactory testing (sniffin sticks test), two brain MRI (at 1.5T and 3.0T)</style>
- Arm 2: <style fontName='DejaVu Sans' isBold='true'>healty controls: clinical examination (UPDRS, Hoehn & Yahr), olfactory testing (sniffin sticks test), two brain MRI (at 1.5T and 3.0T)</style>

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
-

Study Type: **Non-interventional**

Study Type Non-Interventional: **Other**

Allocation: **Non-randomized controlled trial**

Blinding: **[---]***

Who is blinded: **[---]***

Control: **Other**

- Purpose: **Diagnostic**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

To assess the diagnostic value of structural MR findings using routine MRI sequences (T2, T1) at 3.0T versus 1.5T to detect atrophy or signal changes in basal ganglia and infratentorial structures for differential diagnosis of neurodegenerative parkinsonism.

Secondary Outcome

1. To identify structural changes (atrophy, signal changes) in regional brain structures that distinguish APD from PD and healthy controls and that distinguish between the different APDs; 2. To identify DWI/DTI changes in regional brain structures that distinguish PD from healthy controls; 3. To identify DWI/DTI changes in regional brain structures that distinguish APD from PD and healthy controls and that distinguish between the different APDs; 4. To identify grey or white matter changes in regional brain structures using VBM that distinguish APD from patients with PD and healthy controls as well as between the different APDs.

Countries of recruitment

- AT **Austria**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
-

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2011/06/29**

- Target Sample Size: **120**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **30 Years**
- Maximum Age: **85 Years**

Additional Inclusion Criteria

patients:
1. clinical diagnosis of PD, MSA or PSP obtained by a neurologist according to published clinical diagnostic criteria;
2. the patient has the ability to communicate well with the investigator and comply with the requirements of the study;
3. written informed consent is obtained;

healthy controls:
1. the subject has the ability to communicate well with the investigator and comply with the requirements of the study;
2. written informed consent is obtained;

Exclusion criteria

patients:
1. History of other neurological or psychiatric disorders or conditions;
2. the subject has a history of alcohol, narcotic, or any other drug abuse as defined by the Diagnostic and Statistical Manual of the American Psychiatric Association, 4th Edition (DSM-IV);
3. the subject is pregnant;
4. the subject is unsuitable for an MRI study (e.g. Pacemakers);

healthy controls:
1. History of neurological or psychiatric disorders or conditions;
2. the subject has a history of alcohol, narcotic, or any other drug abuse as defined by the Diagnostic and Statistical Manual of the American Psychiatric Association, 4th Edition (DSM-IV);
3. the subject is pregnant;
4. the subject is unsuitable for an MRI study

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Fax: **0043-1-404 20-2399**
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URL: **http://www.oenb.at/**

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*