

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

Trial Description

Title

Electrophysiological characterization of pathological oscillations in Basal-Ganglia-Cortex-Loops and their coupling to muscle activity in patients with Idiopathic Parkinson's disease during the performance of a tapping task.

Trial Acronym

InExPacT

URL of the trial

[---]*

Brief Summary in Lay Language

In this study we would like to investigate how the electrical activity of the brain is altered in Parkinson's patients compared to healthy controls. We use the recording of brain activity via an Electroencephalogramm (EEG) with 128 electrodes that are placed on the heads surface. At the same time, subjects are asked to perform a tapping task in which they either move their index finger synchronously to a given beat or they produce the before heard beat on their own. With this task, we investigate whether Parkinson's patients exhibit greater problems when producing self paced movements rather than externally triggered and whether these problems are accompanied by changes in the communication of brain areas.

Brief Summary in Scientific Language

The idiopathic Parkinson's syndrome is the second most common neurological disease in Germany. Across the country, about 100.000 to 200.000 people suffer from it. At the cellular level, the loss of dopaminergic neurons in the Substantia nigra pars compacta causes the cardinal neurological symptoms like Bradykinesia, Rigor, Tremor and postural instability.

New findings with respect to the development of motor symptoms in Parkinson's disease suggest that the electrical activity of specific brain areas gets pathologically coupled. This hypothesis is based on non-invasive EEG and MEG recordings as well as synchronous recordings of muscle activity.

In the present study, we aim at recording EMGs from three forearm muscles as well as a 128-channel EEG from the head surface. Synchronously to electrophysiological recording, patients and healthy controls perform a finger tapping task consisting of three different conditions: a paced tapping condition where subjects were asked to tap in synchrony with an acoustic stimulus, a self-paced condition where the previously heard beat should be reproduced and a third condition where the acoustic stimulus was presented ten times and turned off afterwards while the rhythm should be maintained.

In previous studies it was shown that Parkinson's patients perform worse



compared to healthy controls in finger tapping tasks and that frequency specific coupling of lateral premotor cortex to supplementary motor area was missing. In addition, physiological coupling between the prefrontal cortex and premotor areas was absent in patients. The latter coupling could be reinstated by levodopa administration.

In the present study, we focus on the difference of externally and internally paced movements with respect to electrical coupling of motor related brain areas. We use a new class of mathematical models for inferring differences within a core motor network between Parkinson's patients and healthy controls to investigate possible impairments with respect to rhythm generation that may be due to pathological alterations of coupling between brain areas.

Organizational Data

- DRKS-ID: **DRKS00008899**
- Date of Registration in DRKS: **2015/10/02**
- 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.: **14-130 , Ethik-Kommission der Medizinischen Fakultät der Universität zu Köln**

Secondary IDs

Health condition or Problem studied

- ICD10: **G20 - Parkinson disease**
- Free text: **Healthy Subjects**

Interventions/Observational Groups

- Arm 1: **healthy control subjects of the same age**
- Arm 2: **Parkinson's patients: EEG recording without medication in the state of bad mobility, "off"-state, standardized dose of dopaminergic drug (Madopar LT equivalent to the morning dose), repetition of the recording in the state of good mobility "on"-state**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*



Study Type: **Interventional**

Study Type Non-Interventional: [---]*

- Allocation: **Non-randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Control group receives no treatment**
- Purpose: **Basic research/physiological study**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Pathological coupling of motor related brain areas in Parkinson's patients compared to healthy subjects

Secondary Outcome

Parkinson's patients exhibit a stronger impairment for self initiated than externally triggered movements.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Neurologie, Köln**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/03/01**
- Target Sample Size: **24**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria



- Gender: **Both, male and female**
- Minimum Age: **30 Years**
- Maximum Age: **80 Years**

Additional Inclusion Criteria

Healthy subjects:

- **Male and female participants between 30 and 80 years of age**
- **Right handed persons**
- **Capability of signing an informed consent**

Parkinson's patients:

- **Male and female patients with the diagnosis of an IPS according to the guidelines of the DGN**
- **Right handed patients**
- **positive motor response to L-Dopa or Apomorphine;**
- **Patients between 30 and 80 (in order to exclude genetic variants of the disease);**
- **time period of the symptoms longer than 4 years (differential diagnosis);**
- **patients have to be able to sign an informed consent;**
- **Ability to cooperate during the measurements**

Exclusion criteria

Healthy subjects:

- **non- "sui juris" patients, underaged persons as well as subjects which are judicially sent to an institution**
- **diagnosis of an idiopathic parkinson syndrom or any other neurological disease**
- **participants that take drugs regularly which influence the nervous system and which can not be stopped the evening before the experiment**
- **severe internal comorbidities**
- **presence of psychiatric diseases**
- **impaired vision or hearing defect that may hinder the testing**
- **pregnant or breast feeding mothers**

Parkinson's patients:

- **non- "sui juris" patients, underaged persons as well as subjects which are judicially sent to an institution**
- **patients that suffer from another neurological disease apart from Parkinsons like Epilepsy, Alzheimers or Dystonia**
- **patients with severe frontal executive disturbances**
- **presence of a Parkinson-Plus-Syndrom like corticobasal degeneration, progressive supranuclear palsy or multisystem atrophy**
- **other hypokinetic movement disorders like MPTP- or manganese intoxication, chorea Huntington, subcortical arteriosclerotic encephalopathy or psychogenic movement disorder**
- **clinically relevant abnormalities in preoperative MR-Images like ischemia, or cerebral atrophy**
- **previous surgeries in the ZNS due to, for example, brain tumors, epilepsy or vascular reasons**
- **severe internal comorbidities**
- **presence of psychiatric diseases**
- **impaired vision or hearing defect that may hinder the testing**
- **pregnant or breast feeding mothers**

Addresses

■ Primary Sponsor

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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.)**

Deutsche Forschungsgemeinschaft

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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.