

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

Trial Description

Title

Networkmodulation in Dystonia patients with Globus pallidus deep brain stimulation with H2O-PET

Trial Acronym

DYSTO-PET

URL of the trial

[---]*

Brief Summary in Lay Language

Dystonia is a disease of the motor systems with inclusion of different body parts and different progression of the disease.

One therapy option is the recently developed deep brain stimulation which modulates the affected brain motor network in a way which improves symptoms of dystonia. The mechanisms of deep brain stimulation are so far not completely understood.

This study aims to show different patterns of blood flow during a motor task with a simple finger movement in patients with and without deep brain stimulation compared to healthy controls. A special focus is to have a closer look on a not affected hand.

We want to show in this study if during the use of an unaffected hand changes in the blood flow can be observed and which effects has the deep brain stimulation on the motor network in dystonia.

Brief Summary in Scientific Language

Dystonia is a disease of the motor systems with inclusion of different body parts and different progression of the disease. The mechanisms of the development of different symptoms from a single affected segment to a generalisation are not known yet. Especially the question of bilateral functional sensorimotor abnormalities in unilateral affected patients are not understood.

One therapy option is the recently developed deep brain stimulation in the globus pallidus internus which modulates the affected brain motor network in a way which improves symptoms of dystonia. The mechanisms of deep brain stimulation are so far not completely understood.

This study aims to show different patterns of blood flow with H2O-positronemissiontomography during a motor task with a simple finger movement in patients with and without deep brain stimulation compared to healthy controls. A special focus is to have a closer look on a not affected hand with electromyography (EMG).

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Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00003137**
- Date of Registration in DRKS: **2011/10/18**
- 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.: **08-246 , Ethik-Kommission der Medizinischen Fakultät der Universität zu Köln**

Secondary IDs

Health condition or Problem studied

- ICD10: **G24 - Dystonia**
- ICD10: [---]* - [---]*



ICD10: [---]* - [---]*

Interventions/Observational Groups

■ Arm 1: **Patients with dystonia without deep brain stimulation**

Examination:

H2O-positron emission tomography (PET) with active and passive finger movement and simultaneous EMG-recording at one timepoint

■ Arm 2: **Patients with dystonia with deep brain stimulation**

Examination:

H2O-positron emission tomography (PET) with active and passive finger movement and simultaneous EMG-recording at one timepoint

■ Arm 3: **Healthy controls**

Examination:

H2O-positron emission tomography (PET) with active and passive finger movement and simultaneous EMG-recording at one timepoint

Characteristics

■ Study Type: **Non-interventional**

■ Study Type Non-Interventional: **Other**

■ Allocation: **Other**

■ Blinding: [---]*

■ Who is blinded: [---]*

■ Control: **Other**

■ Purpose: **Basic research/physiological study**

■ Assignment: **Other**

■ Phase: **N/A**

■ Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*

Primary Outcome

changes in the blood flow in H2O-PET between the following conditions/groups:

- 1. patients in the rest-condition with and without deep brain stimulation**
- 2. patients in the rest-condition with and without dystonia**
- 3. patients with dystonia and deep brain stimulation in the active and passive movement condition**

Secondary Outcome

Changes in the muscular oscillations in the EMG in the following conditions/groups:

- 1. patients in the rest-condition with and without deep brain stimulation**
- 2. patients in the rest-condition with and without dystonia**
- 3. patients with dystonia and deep brain stimulation in the active and passive movement condition**

Countries of recruitment

- **DE Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2010/06/01**
- Target Sample Size: **36**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **80 Years**

Additional Inclusion Criteria

- **male or female patients with cervical or segmental dystonia with or without deep brain stimulation in the globus pallidus internus**
- **diagnosis has to be confirmed with the clinical course and a neurological examination**
- **dystonia has to be bearable after switching the deep brain stimulation**

Exclusion criteria

- **no preoperative coregistered cranial magnetresonancetomography in case of patients with deep brain stimulation**
- **patients with other neurological disorders (e.g. epilepsy, stroke, Alzheimer's dementia)**
- **life-threatening diseases**
- **severe psychiatric disorders**
- **obvious premorbid mental deficits**

- **pregnant women**

Addresses

■ Primary Sponsor

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Sources of Monetary or Material Support

■ Institutional budget, no external funding (budget of sponsor/PI)

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Deutsches Register
Klinischer Studien

German Clinical
Trials Register

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/05/31**

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.*