Deep Brain Stimulation (DBS) of the Globus pallidus (GP) in Huntington’s disease: A prospective, randomised, controlled, international, multi-centre study (HD-DBS)

<table>
<thead>
<tr>
<th>STUDY DESIGN</th>
<th>Prospective, randomised, double blind, parallel group, sham-controlled, multi-centre superiority trial.</th>
</tr>
</thead>
<tbody>
<tr>
<td>TREATMENT</td>
<td>Bilateral stereotactic implantation of quadripolar electrodes (Medtronic Inc., 3387) into the GP and ACTIVA® PC stimulator for chronic high-frequency stimulation.</td>
</tr>
</tbody>
</table>
| AIM OF THE STUDY      | • to show superiority of DBS on motor function in the stimulation group compared to stimulation-off group  
                          • to show, that DBS is an alternative to medication therapy  
                          • to prove the efficacy and safety of pallidal DBS in HD patients |
| PRIMARY ENDPOINT      | Difference between groups in the UHDRS total motor score (UHDRS-TMS) at 12 weeks postoperatively compared to baseline. |

### CRITERIA FOR INCLUSION
- Clinically symptomatic and genetically confirmed HD (number of CAG repeats ≥ 36)  
  - Age ≥18 years  
  - Moderate stage of the disease (UHDRS motor score ≥ 30)  
  - Chorea despite best medical treatment (UHDRS chorea subscore ≥ 10)  
  - Mattis Dementia Rating Scale ≥ 120 (or > 80% of items testable independently from motor impairment)  
  - Patient has stable medication prior six weeks before inclusion  
  - Signed informed consent

### CRITERIA FOR EXCLUSION
- Juvenile HD (Westphal variant) or predominant bradykinesia  
  - Postural instability with UHDRS retropulsion score > 2  
  - Severe comorbidity compromising operability and/or life expectancy and/or quality of life during the trial duration (e.g. cancer with life expectancy < 6 months, NYHA 3 and 4 rising the anaesthetic risk according to the anaesthesiologist)  
  - Acute suicidality  
  - Acute psychosis (symptoms within previous 6 months)  
  - Participation in any interventional clinical trial within 2 months before screening  
  - Cortical atrophy grade 3  
  - Patients with risk of coagulopathies and/or increased risk of haemorrhage  
  - Patients with an implanted pacemaker or defibrillator  
  - Pregnancy and lactation
Contact details:

**Questions in general:**

**Jan Vesper (Düsseldorf)**  
Tel.: +49 211 81 18408  
Mobil: +49 (0) 151 64936249  
jan.vesper@med.uni-duesseldorf.de

**Alfons Schnitzler (Düsseldorf)**  
Tel.: +49 211 81-17893  
Schnitza@med.uni-duesseldorf.de

**General EHDN Contact for HD-DBS:**

**Pauline Kleger (EHDN)**  
Tel.: +49 731 50063106  
Mobile: +49 174 9404718  
Pauline.Kleger@uniklinik-ulm.de

**Further information:**

https://www.euro-hd.net/html/projects/dbs