

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

STUDY DESIGN	Prospective, randomised, double blind, parallel group, sham-controlled, multi-centre superiority trial.
TREATMENT	Bilateral stereotactic implantation of quadripolar electrodes (Medtronic Inc., 3387) into the GP and ACTIVA® PC stimulator for chronic high-frequency stimulation.
AIM OF THE STUDY	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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

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Further information:

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