Trial Description

Title
Deep brain Stimulation for Tremor Tractographic Versus Traditional

Trial Acronym
DISTINCT

URL of the trial
[---]*

Brief Summary in Lay Language
This is a monocentric, randomized, controlled, 2 arms, interventional, observer-blinded feasibility trial.

Patients suffering from essential tremor (ET) will be treated with Deep Brain Stimulation (DBS). For the implantation of the DBS electrodes and the DBS system (Activa INS, Medtronic) patients will randomized either to conventional stereotactic surgery of thalamic/subthalamic region with short anesthesia or to MR-tractography guided stereotactic surgery with target point of the dentato-rubro-thalamic bundle (DRT) in general anesthesia.

Patients will visit the study center at screening, baseline/neurosurgery, six and twelve months after neurosurgery.

Brief Summary in Scientific Language
In this monocentric, randomized, controlled, 2 arms, interventional, observer-blinded feasibility trial patients suffering from therapy resistant essential tremor (ET) will be treated with Deep Brain Stimulation (DBS).

After screening (e.g. obtaining informed consent, assessment of inclusion/exclusion criteria etc.) patients will be randomized to one of the following groups:

Group 1 (conventional):
Conventional AC-PC based DBS implantation in the thalamic/subthalamic region (Vim-cZI) starting as awake surgery with a brief general anesthesia for stimulator implantation at the end of surgery.

Group 2 (tractographic):

Magnetic resonance (MR)-tractography guided DBS implantation in the dentato-rubro-thalamic bundle (DRT) in general anesthesia

At the baseline/neurosurgery visit Quality of Life (QoL) and other parameters will assessed. Medtronic’s Activa INS DBS will be implanted according to randomization. DBS will be started approximately one month after surgery and will be applied as per routine.

Patients will have their routine visits. For this trial data of the (routine) visits six and twelve months after neurosurgery will be collected.

Patients receive DBS after the end of the trial according to local standards.

Organizational Data

- DRKS-ID: DRKS00008913
- Date of Registration in DRKS: 2015/07/13
- Date of Registration in Partner Registry or other Primary Registry: 2015/06/30
- Investigator Sponsored/Initiated Trial (IST/IIT): yes
- Ethics Approval/Approval of the Ethics Committee: [---]*
- (leading) Ethics Committee Nr.: [---]*

Secondary IDs

- Primary Registry-ID: NCT02491554 (ClinicalTrials.gov)
- Sponsor-ID: P000847 (University Hospital Freiburg)

Health condition or Problem studied

- Free text: Essential Tremor

Interventions/Observational Groups
Arm 1: **Device:** Conventional AC-PC based implantation of ACTIVA INS DBS system  
Arm 2: **Device:** MR-tractography guided implantation of ACTIVA INS DBS system

**Characteristics**

- Study Type: **Interventional**  
- Study Type Non-Interventional: [---]*  
- Allocation: **Randomized controlled trial**  
- Blinding: [---]*  
- Who is blinded: investigator/therapist, assessor  
- Control: **Active control**  
- Purpose: **Treatment**  
- Assignment: **Parallel**  
- Phase: **N/A**  
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*

**Primary Outcome**

- Tremor reduction defined by the difference in FTMTRS at 6 months after intervention to baseline; time frame: Baseline, 6 months after neurosurgery;  
Tremor reduction defined by the difference in Fahn-Tolosa-Marin Tremor Rating Scale (FTMTRS) at 6 months after intervention to baseline

**Secondary Outcome**

- Effective tremor reduction at 12 months after intervention; time frame: Baseline, 12 months after neurosurgery; Effective tremor reduction (an FTMTRS score reduction by 50% compared to baseline is regarded as “response”) at 12 months after intervention  
- Tremor reduction measured by tremor analysis at baseline and 6 and 12 months after intervention; time frame: Baseline, 6 and 12 months after neurosurgery;  
Tremor reduction will be measured by tremor analysis (an accelerometric examination); Unit: Hertz (Hz)  
- Tremor reduction measured by calculation of total power at baseline and 6 and 12 months after intervention; time frame: Baseline, 6 and 12 months after neurosurgery;  
Tremor reduction will be assessed during Electromyography (EMG) by the calculation of total power; Unit: mg², with g=9.81 m/s²  
- Quality of Life: QUEST, SF-36; time frame: Baseline, 6 and 12 months after neurosurgery;  
Quality of Life assessed by Quality of Life Essential Tremor Questionnaire (QUEST) and Short Form (36) Health Survey  
- Size of VAT; time frame: Day 0 (Day of neurosurgery); Size of Volume of activated tissue (VAT)  
- Effective contact position with respect to DRT and AC-PC coordinates; time frame: Day 0 (Day of neurosurgery); Effective contact position of stimulation electrodes (with respect to the Dentato-rubro-thalamic bundle (DRT) and anterior commissure (AC) - posterior comissure (PC) line (ACPC) coordinates)
- Duration of neurosurgery; time frame: Day 0 (Day of neurosurgery); Duration of neurosurgery (time points of mounting frame, start surgery, stop surgery (=dismounting frame)
- Changes in BDI; time frame: Baseline, 6 and 12 months after neurosurgery; psychiatric assessment: changes in Beck's Depression Inventory (BDI)
- Assessment of (Serious) Adverse Events related to intervention; time frame: Up to 12 months after neurosurgery

Countries of recruitment

- DE Germany

Locations of Recruitment

- University of Freiburg - Medical Center - Dept. of Stereotactic and Functional Neurosurgery, Freiburg

Recruitment

- Planned/Actual: [---]*
- (Anticipated or Actual) Date of First Enrollment: 2015/07/31
- Target Sample Size: 24
- Monocenter/Multicenter trial: [---]*
- National/International: [---]*

Inclusion Criteria

- Gender: Both, male and female
- Minimum Age: 25 Years
- Maximum Age: 80 Years

Additional Inclusion Criteria

1. Male or female patients aged ≥ 25 and ≤ 80 years

2. Patients with Essential Tremor according to the criteria of the consensus statement of the movement disorders society (Deuschl et al. 1998) are included with a medical treatment resistant and disabling postural and/or intentional tremor.

3. FTMTRS to be completed within 42 days prior surgery

4. Stable tremor medication for at least 3 months prior inclusion
5. Written informed consent

Exclusion criteria

1. Major Depression with suicidal thoughts or suicidal thoughts in history
2. Dementia (Mattis Dementia Rating Score ≤ 130)
3. Acute psychosis
4. Patient incapability
5. Nursing care at home
6. Surgical contraindications
7. Medications that are likely to cause interactions in the opinion of the investigator
8. Known or persistent abuse of medication, drugs or alcohol
9. Persons who are in a relationship of dependence/employment with the sponsor or the investigator
10. Fertile women not using adequate contraceptive methods: female condoms, diaphragm or coil, each used in combination with spermicides; intra-uterine device; hormonal contraception in combination with a mechanical method of contraception;
11. Current or planned pregnancy, nursing period

Addresses

- Primary Sponsor
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  E-mail: [----]*
  URL: [----]*

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Collaborator, Other Address

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Sources of Monetary or Material Support

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

Telephone: [---]*
Fax: [---]*
E-mail: [---]*
URL: [---]*

Status

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

Trial Publications, Results and other documents


Further trial documents

Further trial documents

Further trial documents

Further trial documents

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

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.

- Translation on version: [---]*
- Last processed date by ClinicalTrials.gov: 2015/07/09

* 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.