

Trial Description

Title

Comparative Imaging of the Hippocampal Formation in Epilepsy Patients at 3 and 7 Tesla: Is There a Diagnostic Benefit in Ultra-High-Field MRI?

Trial Acronym

HIPPOTLE

URL of the trial

[---]*

Brief Summary in Lay Language

Patients with epileptic seizures that are generated in the temporal lobe of the brain frequently have pathological changes to the so-called hippocampus. This is a developmentally very old brain structure involved in memory functions, which is why patients with temporal lobe epilepsy frequently suffer additional memory problems. Pronounced changes to the hippocampus can be seen with standard MRI scanning devices with 1.5 or 3 Tesla magnetic field strength. However, up to 30 % of all patients have normal MRI scans, even if hippocampal pathologies must be assumed due to memory deficits. In the present study, we want to use a more powerful MRI device (7 Tesla field strength) to produce higher resolution images; we assume that it can yield pathological changes to the hippocampus that couldn't be seen at 3 Tesla.

Brief Summary in Scientific Language

In temporal lobe epilepsy, hippocampal damage can often be assumed due to EEG pathologies and symptoms. However, in 20 to 30 % of all cases, standard MRI at 1.5 or 3 Tesla result normal (Winston et al. 2013). In the present study, we want to use ultra-high field MRI (7 Tesla) and new scanning protocols (MP2RAGE, Marques et al. 2010) to increase the detection rate of subtle morphological pathologies. An MRI-detectable hippocampal lesion is one of the strongest predictors for a successful surgical intervention in pharmacoresistant epilepsies; therefore, improved imaging techniques might lead to better outcome of e.g. amygdalohippocampectomies in future presurgical diagnostics.

Organizational Data

- DRKS-ID: **DRKS00005649**
- Date of Registration in DRKS: **2014/01/15**
- 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.: **266-13-15072013 , Ethikkommission an der**



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Medizinischen Fakultät der Universität Leipzig

Secondary IDs

- Universal Trial Number (UTN): **U1111-1152-1543**

Health condition or Problem studied

- ICD10: **G40.2 - Localization-related (focal)(partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures**

Interventions/Observational Groups

- Arm 1: **Patients with temporal lobe epilepsy and normal 3 Tesla MR-images**
- Arm 2: **Patients with temporal lobe epilepsy and corresponding lesions in 3 Tesla-MR-images**
- Arm 3: **Patients with temporal lobe epilepsy and additional extratemporal focus (dual pathology)**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Other**
- Purpose: **Diagnostic**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Demonstration of hippocampal pathologies at 7 T taht weren't detectable at 3 T

Secondary Outcome

Assessment of normal distribution of quantitative MRI-values for healthy controls and epilepsy patients

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Epilepsiezentrum Berlin-Brandenburg, Berlin**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2014/01/23**
- Target Sample Size: **80**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Temporal lobe epilepsy

Exclusion criteria

Exclusion criteria of MRI (pace makers, metal implants, large tattoos close to the head, claustrophobia, etc.)

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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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.