



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

## Trial Description

### Title

**Cryptogenic epilepsy: presurgical evaluation and clinical outcome**

### Trial Acronym

**EPICRYPT**

### URL of the trial

**[---]\***

### Brief Summary in Lay Language

**In cryptogenic epilepsy, high resolution magnetic resonance imaging (MRI) is normal. An extensive presurgical, often invasive, diagnostic is needed in order to prove the potential of surgery as a treatment option. When a brain area can be identified as the cause of epilepsy, a removal of this brain area can be performed, with the goal of seizure freedom. This type of surgery is called resection. The seizure outcome of such operations is according to the literature worse compared to epilepsy patients with an abnormal magnetic resonance imaging. Goal of this study is the outcome assessment of resective surgeries for patients with normal MRI and to evaluate the contribution of the diverse diagnostic tools used before the operation.**

### Brief Summary in Scientific Language

**Cryptogenic epilepsies represent the most challenging cases among medically resistant epilepsies. In these epilepsies, high resolution magnetic resonance imaging does not show any potential epileptogenic lesion. An extensive presurgical diagnostic is needed in order to prove the potential of a tailored resection as a therapeutic option. This presurgical diagnostic involves a number of noninvasive and invasive (with intracranial electrodes) diagnostic procedures. When an epileptogenic area can be identified and does not interfere with eloquent, not resectable brain areas, a resection of this brain area can be performed, with the goal to render the patient seizure-free. The seizure outcome of such operations is according to the literature worse compared to epilepsy patients with a lesional magnetic resonance imaging. Goal of this study is the retrospective outcome assessment of resective surgeries for magnetic resonance imaging negative epilepsies and to evaluation the contribution of the diverse presurgical diagnostic tools.**

## Organizational Data



- DRKS-ID: **DRKS00010013**
- Date of Registration in DRKS: **2016/04/12**
- 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.: **110/16 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **G40 - Epilepsy**

## Interventions/Observational Groups

- Arm 1: **Retrospective study of long-term outcome after resective surgery for cryptogenic epilepsy and evaluation of the presurgical diagnostic modalities. Restrospective evaluation of histopathology. Evaluation of the role that an image post-processing analysis may have.**

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: [---]\*
- Who is blinded: [---]\*
- Control: **Uncontrolled/Single arm**
- Purpose: **Prognosis**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

## Primary Outcome

**Seizure outcome according to Engel classification and neurological Outcome 1 year after surgery**

## Secondary Outcome

**Seizure outcome according to Engel classification and neurological Outcome in the last follow-up examination**

## Countries of recruitment

- **DE Germany**

## Locations of Recruitment

- University Medical Center **Freiburg im Breisgau**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/09/01**
- Target Sample Size: **33**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

## Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **65 Years**

## Additional Inclusion Criteria

**pharmacoresistant epilepsy an non-lesional 3 Tesla MRI, resective surgery, time: from 2004-2015**

## Exclusion criteria

**lesional MRI, exclusively not resective surgery (e.g vagus nerve stimulaor, multiple subpial transections)**

## Addresses

- **Primary Sponsor**  
**Neurochirurgie**



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**Primary Sponsor**

**Neurochirurgie**

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■ **Contact for Scientific Queries**

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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 continuing**
- 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.