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# Evaluation of neurosurgical resection strategies in temporal lobe epilepsy

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 11/08/2008 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 21/08/2008 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 28/08/2008 | Nervous System Diseases | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

## Study information

**Scientific Title**
Prospective and randomised multicentre trial investigating the pros and cons of different extent of mesial resection in surgery for mesial temporal lobe epilepsy

**Study objectives**
There is an ongoing debate about the mesial resection extent in the surgical treatment of temporal lobe (TL) epilepsy patients and its relation to seizure freedom and neuropsychological outcome. Surgical resection strategies developed from larger resections removing up to 2/3 of the temporal lobe to more selective and smaller resection types.

The objective of this study is to assess the significance of the extent of resection of mesial structures (hippocampus and parahippocampus) to achieve seizure freedom after surgery for temporal lobe epilepsy.

The main goals of this project are to test two hypotheses:
1. Smaller TL resections are associated with less neuropsychological deterioration
2. Post-operative seizure freedom is comparably good in smaller mesial resection

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics approval received from the Ethics Committee of the University of Bonn Medical Centre on the 2nd February 2001 (ref: 237/00)

## Primary study design
Interventional

## Study design
Prospective, interventional, randomised multicentre study

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Intractable mesial temporal lobe epilepsy (MTLE)

## Interventions
As part of the presurgical evaluation patients underwent neuropsychological testing and MRI scanning. Healthy volunteers also underwent neuropsychological testing to serve as a control group regarding the cognitive abilities of the patients.

Patients were randomised to either a short (2.5 cm of hippocampal resection) or a long (3.5 resection length) resection group. The length of resection was to be determined intra-operatively after the opening of the temporal horn by using millimetre paper from the anterior tip of the temporal horn backwards placed on the hippocampal head along its length axis. Furthermore, manual volumetry of structural MRI datasets was used to evaluate the intended resection length.

Post-operatively, patients are seen for MRI-scanning, neuropsychological testing and medical consultation 3, 6 and 12 months after surgery.

## Intervention Type
Other

## Phase
Not Specified

## Primary outcome(s)
Seizure freedom at one year after surgery: defined as class I in the Engel Outcome Scale. The Engel Outcome Scale is administered post-operatively and determines the improvement

/worsening after surgical intervention as follows:
1. Engel class I: seizure-free
2. Engel class II: almost seizure-free
3. Engel class III: significant seizure reduction
4. Engel class IV: no significant improvement

Patients belonging to Engel class I are termed as seizure free, the remaining patients (Engel II - IV) as non-seizure free patients in the present study.

Secondary analysis:
Seizure freeness in subgroups (based on neuropathological analyses), e.g. patients with mesial temporal sclerosis.

## Key secondary outcome(s)

Neuropsychological testing:
Each patient underwent comprehensive neuropsychological testing pre-operatively and 12-months post-operatively. For the comprehensive purpose of this study, various neuropsychological parameters are aggregated, resulting in scores for seven major cognitive domains:
1. Verbal learning and memory: two parallel versions of a pre- and post-operative verbal learning test (Verbaler Lern- und Merkfähigkeitstest [VLMT]). The VLMT (German adaptation of the Rey Auditory Verbal Learning Test) requires five trials of learning and recall of a word list consisting of 15 words, free recall immediately after distraction (learning/recall of a second list in one trial) and a recall after a half-hour delay, which is followed by a recognition trial (list with original words plus distractors).
2. Figural learning and memory was obtained using the DCS-R, a German revised version of the DCS, a design list learning test (Diagnostikum für Zerebralschädigung)
3. Language functions:
3.1. Confrontation naming, Boston Naming Test
3.2. Phonematic and semantic fluency
3.3. Token Test, a subtest of the Aachener Aphasie-Test (a german test battery for aphasia) which is seen to measure verbal comprehension
4. Attention functions:
4.1. D2-Test, a letter cancellation test
4.2. The c.I.T., a short test to measure cerebral insufficiency (Kurztest für cerebrale Insuffizienz)
5. Psychomotor speed, mental tracking and cognitive flexibility:
5.1. Trail Making Test A and B (TMT-A/B)
5.2. Motoric sequences after Lurija
5.3. Purdue Pegboard
5.4. Finger Tapping Test
6. Visual and spatial abilities:
6.1. Subtest LPS-7 of the Leistungsprüfsystem (LPS), a german intelligence battery
6.2. The Mosaic-Test, a subtest of the German version of the Wechsler Adult Intelligence Scale-Revised (HAWIE-R)
6.3. Labyrinth test
7. Behaviour and personality features:
7.1. German version of the Beck Depression Inventory (BDI)
7.2. FPZ (Fragebogen zur Persönlichkeit bei zerebralen Erkrankungen), an unpublished German CNS-disease related personality questionnaire
7.3. Quality of Life Inventory in Epilepsy, 10-item version (QOLI-10)

All neuropsychological results were classified into five categories (0 = noticeably abnormal, 1 = moderately abnormal, 2 = borderline, 3 = without pathological findings, 4 = above average).

### Completion date
30/06/2008

## Eligibility

### Key inclusion criteria
1. Patients suffering from intractable temporal lobe epilepsy
2. Drug resistance: seizure history lasting more than two years
3. Pre-surgical evaluation led to the recommendation of either a partial temporal lobe resection combined with amygdalohippocampectomy or a more restricted selected selective amygdalohippocampectomy (SAH)
4. Only cases with mesial involvement were included
5. Patients had to be at least 18 years old (either sex) and able to understand the study plan
6. Written informed consent

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex
All

### Key exclusion criteria
1. Previous temporal lobe surgery
2. Inability to do undergo neuropsychological testing because of retardation or foreign language
3. Mesial resection restricted to uncus and amygdala
4. No usable pre-operative magnetic resonance imaging (MRI) for volumetrical analyses
5. Pathology not allowing for randomisation (far dorsal reaching resection necessary)

### Date of first enrolment
15/10/2002

### Date of final enrolment
30/06/2008

## Locations

### Countries of recruitment

Germany

**Study participating centre**
**Sigmund-Freud-Str. 25**
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# Sponsor information

**Organisation**
German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany)

**ROR**
https://ror.org/018mejw64

# Funder(s)

**Funder type**
Research council

**Funder Name**
German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany)

# Results and Publications

## Individual participant data (IPD) sharing plan

**IPD sharing plan summary**
Not provided at time of registration

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | Cortical damage results (): | 01/02/2004 | | Yes | No |
| Results article | Neuropsychological outcome results (): | 01/07/2004 | | Yes | No |
| Results article | One year follow-up results (): | 01/08/2004 | | Yes | No |

| | | | | | |
|---|---|---|---|---|---|
| Results article | Children and aduly comparative study results (): | 01/12/2005 | | Yes | No |
| Results article | MRI volumetry results (): | 01/03/2007 | | Yes | No |
| Results article | Memory and non-memory function results (): | 01/01/2008 | | Yes | No |
| Results article | Cognitive rehabilitation results (): | 01/04/2008 | | Yes | No |
| Results article | Prospective study results (): | 01/08/2008 | | Yes | No |
| Other publications | Research (): | 01/12/2007 | | Yes | No |
| Other publications | Comment (): | 01/02/2008 | | Yes | No |
| Other publications | Review (): | 01/08/2008 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |