

# Randomised controlled trial on the impact of collateral damage and disconnections on memory outcome after temporal lobe epilepsy surgery and the relevance of surgically caused memory decline for every day activities and functioning

|                                        |                                                      |                                                      |
|----------------------------------------|------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>30/09/2008   | <b>Recruitment status</b><br>No longer recruiting    | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>31/10/2008 | <b>Overall study status</b><br>Completed             | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>31/10/2008       | <b>Condition category</b><br>Nervous System Diseases | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                      | <input type="checkbox"/> Results                     |
|                                        |                                                      | <input type="checkbox"/> Individual participant data |
|                                        |                                                      | <input type="checkbox"/> Record updated in last year |

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

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Johannes Schramm

**Contact details**  
Klinik für Neurochirurgie  
Sigmund-Freud-Str. 25  
Bonn  
Germany  
53105

## Additional identifiers

**Protocol serial number**  
Sonderforschungsbereich (SFB) TR3 subproject A1

# Study information

## Scientific Title

Subtemporal versus transsylvian approach for selective amygdala-hippocampectomy: a randomised controlled trial on the epileptological and cognitive outcome

## Study objectives

The aim of the study is to evaluate pre- and post-operative verbal episodic memory, frontal lobe executive functions and reward learning as a function of surgically-caused cortical lesions and dissections of fibre tracts from and to the temporal lobe structures.

As the main surgical variation will be that of a preservation or dissection of the temporal stem, using a subtemporal versus a transsylvian approach, differences due to this variation are expected:

1. Preserving the temporal stem (subtemporal approach) results in a better crosstalk between frontal executive and temporal memory functions. Therefore memory aspects of organisation, differentiation, recognition (source memory) theoretically can be expected to be better preserved after the subtemporal approach as compared to the transsylvian approach.
2. Partial disconnection of the temporal stem (transsylvian approach) is possibly expected to result in a more pronounced effect of reward learning as the importance of the functional connection between temporal and frontal structures for this function has been discussed recently
3. The relevance of cognitive development and seizure control for quality of life and their implication for the patients' every day life are another topic of interest. How much memory decline will be accepted in favor of seizure freeness? With an unfavourable outcome in terms of seizure as well as memory outcome one might assume a negative impact on the patients' memory-dependent activities and their quality of life that might go along with higher rates of depression.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

University of Bonn Medical Centre Ethics Committee approval received on the 30th April 2008 (ref: 032/08)

## Study design

Prospective, interventional, randomised single-centre study

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Intractable mesial temporal lobe epilepsy (MTLE)

## Interventions

As part of the pre-surgical evaluation patients and healthy controls will be neuropsychologically tested and investigated with functional as well as structural MRI. Patients were then randomised to either a subtemporal or a transsylvian surgical approach, resulting in a preservation (subtemporal approach) or dissection (transsylvian approach) of the temporal stem. 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)**

Neuropsychological outcome in memory and non-memory functions as well as in brain activation in three fMRI paradigms will serve as dependent measures. Each patient will undergo comprehensive neuropsychological testing pre-operatively and 12 months post-operatively. The following tests will be applied:

1. Verbal learning and memory: two parallel versions of a pre- and post-operative Verbal Learning Test (VLMT- Verbaler Lern- und Merkfähigkeitstest). 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. FMRI investigation: a new fMRI paradigm will be established for reward learning

All respective measures (primary and secondary outcome measures) will be obtained pre-operatively and 12 months post-operatively.

## **Key secondary outcome(s)**

These address the question of the patients' quality of life, personality, depression and memory-dependent activities, which will be assessed using the following questionnaires:

1. A German version of the Beck Depression Inventory (BDI)
2. FPZ (Fragebogen zur Persönlichkeit bei zerebralen Erkrankungen), an unpublished German CNS-disease related personality questionnaire
3. A German adaptation of the QOLIE-10 (Quality of Life Inventory in Epilepsy, 10-Item version), a brief questionnaire to screen for quality of life in epilepsy
4. "Memory activities in every day life" MADL, a questionnaire on frequencies of memory dependent everyday activities. The MADL, is a new, unpublished rating scale which has been developed as part of a workshop of the International League against Epilepsy in Venice and is intended to fill the gap between neuropsychological memory impairment, subjective opinion and memory in every day life.

All respective measures (primary and secondary outcome measures) will be obtained pre-operatively and 12 months post-operatively.

**Completion date**

30/06/2012

## Eligibility

**Key inclusion criteria**

1. Both males and females
2. Patients suffering from intractable temporal lobe epilepsy
3. Drug resistance
4. Presurgical evaluation led to the recommendation of selective amygdalo-hippocampectomy (SAH)
4. Only cases with an magnetic resonance imaging (MRI)-based diagnosis of Ammon's horn sclerosis will be included
5. Adults (greater than 18 years)
6. Patients have to be able to understand the study plan and give 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 undergo neuropsychological testing because of retardation or insufficient German

language skills  
3. Gravidity  
4. Claustrophobia  
5. Metallic implants/non-removable piercings  
6. Neurological/psychiatric illness

**Date of first enrolment**

15/10/2008

**Date of final enrolment**

30/06/2012

## **Locations**

**Countries of recruitment**

Germany

**Study participating centre**

Klinik für Neurochirurgie

Bonn

Germany

53105

## **Sponsor information**

**Organisation**

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

**ROR**

<https://ror.org/018meiw64>

## **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? |
|-----------------------------------------------|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |
| <a href="#">Study website</a>                 | Study website                 | 11/11/2025   | 11/11/2025 | No             | Yes             |