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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

Submission date
30/09/2008

Recruitment status
No longer recruiting

Registration date
31/10/2008

Overall study status
Completed

Last Edited
31/10/2008

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.meb.uni-bonn.de/epileptologie/sfb-tr3/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
General information concerning Epilepsy surgery can be found on the website of our hospital: http://www.ukb.intern/42256BC8002AF3E7/vwWebPagesByID /3BB88E00CAE320D2C12571D40063EFB9 Patient information concerning our subproject A1: http://www.ukb.intern/42256BC8002AF3E7/vwWebPagesByID /8BE510569EF540CCC12571D40056E8CD and http://www.meb.uni-bonn.de/epileptologie/sfb-tr3/index.html

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 measure
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.

Secondary outcome measures
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.

Overall study start date
15/10/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

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)

Sponsor details
Kennedyallee 40
Bonn
Germany
53175

Sponsor type
Research council

Website
http://www.dfg.de

ROR
https://ror.org/018mejw64

Funder(s)

Funder type
Research council

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration