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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

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
N/A

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)

Study design
Prospective, interventional, randomised multicentre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information can be found at: http://www.ukb.intern/42256BC8002AF3E7/vwWebPagesByID/8BE510569EF540CCC12571D40056E8CD

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 measure
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.

Secondary outcome measures
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).

Overall study start date
15/10/2002

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

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
200 to 250

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
Bonn
Germany
53105

Sponsor information

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

Sponsor details
Kennedyallee 40
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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

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
Other publications	Research ():	01/12/2007		Yes	No
Results article	Memory and non-memory function results ():	01/01/2008		Yes	No
Other publications	Comment ():	01/02/2008		Yes	No

Results article	Cognitive rehabilitation results ():	01/04/2008	Yes	No
Other publications	Review ():	01/08/2008	Yes	No
Results article	Prospective study results ():	01/08/2008	Yes	No