Language and memory function in surgical patients with temporal lobe epilepsy

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We aim to investigate language production and verbal episodic memory performance, as well as the respective associated neural (co-)organisation of the two systems observed postsurgery in people with left temporal epilepsy in comparison to healthy...

Ethical review	Approved WMO
Status	Pending
Health condition type	Seizures (incl subtypes)
Study type	Observational non invasive

Summary

ID

NL-OMON56502

Source ToetsingOnline

Brief title EpiLang

Condition

• Seizures (incl subtypes)

Synonym epilepsy, seizures

Research involving Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen Source(s) of monetary or material Support: NWO

Intervention

Keyword: epilepsy surgery, language, memory, temporal lobe

Outcome measures

Primary outcome

Main study parameter is the task-related brain activity measured with

magnetoencephalography, together with patients* language and memory performance

based on experimental and standardised tests.

Secondary outcome

Study description

Background summary

Our knowledge of post-surgery cognitive outcomes for people with temporal lobe epilepsy has been primarily shaped by investigations in the memory domain. However, typically, apart from the neural structures associated with memory function (such as hippocampi), anterior and basal cortical areas of the left temporal lobe linked to language function are also removed during surgery. Although assessed with basic neuropsychological tests pre- and post-operation, language function remains largely understudied despite the fact that many patients experience difficulties with finding words while speaking. Only recently researchers started systematically exploring the impact of location and size of resection on language abilities, with functional data on post-operative organisation of function remaining scarce.

Study objective

We aim to investigate language production and verbal episodic memory performance, as well as the respective associated neural (co-)organisation of the two systems observed post-surgery in people with left temporal epilepsy in comparison to healthy controls.

Study design

It is an observational study to assess patients* language and memory abilities

after surgery. The participants will have their T1 and T2-weighted structural MRI brain scans made. Furthermore, they will perform picture-naming and memory tasks while the magnetoencephalography is recorded. Finally, they will perform the behavioural tests, namely, a visual object naming (Boston Naming Test), an auditory object naming and an episodic memory (15-word test) test.

Study burden and risks

Experimental measures as well as the procedures of magnetoencephalography and magnetic resonance imaging implicate minimal burden and risk to participants. Patients do not directly benefit from their participation in terms of therapeutic gain, but they obtain information about their cognitive abilities and realise the intrinsic motivation frequently expressed by the participants. Participants can withdraw from the study at any time point. The findings of this study will yield further insights into the organization of the language network after temporal lobe epilepsy surgery, including in relation to memory function.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

- Native speakers of Dutch;
- 18 y.o. and older;

- Undergone epilepsy surgery in the mesial temporal/ temporal lobe (left hemisphere);

- At least 1 year after surgery;
- Have seizures under control (combination of medication and surgery);
- Have normal IQ and are able to provide informed consent

Exclusion criteria

- Uncontrollable seizures;
- Severe cognitive deficits post-surgery;
- Neurological and psychiatric disorders (other than epilepsy);
- Large and/or ferromagnetic metal parts in the head (except for a dental wire);
- Implanted cardiac pacemaker or neurostimulator;
- Claustraphobia;
- Pregnancy;
- Use of psychotropic or recreational drugs.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-11-2023
Enrollment:	50
Туре:	Anticipated

Medical products/devices used

Registration:

No

Ethics review

Approved WMO	
Date:	15-02-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register CCMO **ID** NL85184.091.23