

Language and EEG characteristics in brain tumour patients: Can we predict language outcome after surgery?

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Main objectives:- Investigating the relation between language functioning and resting-state EEG characteristics in brain tumour patients.- Predicting language outcome after brain tumour surgery, on the basis of pre-operative EEG characteristics....

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nervous system neoplasms benign
Study type	Observational non invasive

Summary

ID

NL-OMON46261

Source

ToetsingOnline

Brief title

Language and EEG characteristics in brain tumour patients

Condition

- Nervous system neoplasms benign
- Nervous system, skull and spine therapeutic procedures

Synonym

'(low-grade) brain tumours', 'gliomas', 'meningiomas'

Research involving

Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Brain Neoplasms, Electroencephalography, Language Disorders, Neurosurgery

Outcome measures

Primary outcome

- Language abilities of low-grade glioma and meningioma patients before surgery, shortly after surgery, and at the long-term follow-up.
- The relation between language functioning and resting-state EEG characteristics in brain tumour patients.
- Pre-operative EEG characteristics that predict language outcome after brain tumour surgery.

Secondary outcome

- Network characteristics that are associated with specific linguistic deficits.
- Associations between language and performance in other cognitive domains.
- The relation between the severity of the language disorder and the quality of life in brain tumour patients before and after surgery.

Study description

Background summary

Primary low-grade brain tumours can cause language deficits that affect the quality of life. These language deficits do not always recover after brain tumour surgery. Several factors can have an influence on the course of recovery, such as tumour grade and/or the extent of an intact neural network. Previous studies related slow-wave brain activity and neural network characteristics to cognitive functioning in brain tumour patients (e.g. Bosma et al., 2008, 2009), but the relation between brain activity and functional networks on one hand and language functioning on the other has not been investigated yet. The current study aims to find predictors for language outcome after surgery of a low-grade glioma or meningioma, by using

resting-state electroencephalography (EEG).

Study objective

Main objectives:

- Investigating the relation between language functioning and resting-state EEG characteristics in brain tumour patients.
- Predicting language outcome after brain tumour surgery, on the basis of pre-operative EEG characteristics.

Secondary objectives:

- Examining network characteristics that are associated with specific linguistic deficits.
- Studying how language is related to other cognitive functions in brain tumour patients.
- Revealing how the severity of the language disorder is related to the quality of life in brain tumour patients before and after surgery.

Study design

This is a longitudinal observational study consisting of two patient groups and a control group without brain injury. The patient groups will get an EEG recording, language assessment, a few neuropsychological tests, and questionnaires before surgery. The language assessment, neuropsychological tests, and questionnaires will be repeated twice after surgery: 1,5-3 months and 1 year post-operatively. A EEG will be performed twice in patientgroup 1 (preoperative and 1 year postoperative). The control group will be assessed with an EEG recording, a spontaneous speech interview and a questionnaire.

Study burden and risks

EEG recording is performed only once, before surgery in patientgroup 2 and twice in patientgroup 1 (preoperative and 1 year postoperative). This is a standard procedure in most brain tumour patients, because of suspected epileptic seizures, and is completely safe.

The language assessment, neuropsychological tests, and questionnaires will be conducted thrice: before, 1.5-3 months after, and 1 year after surgery. No risks are associated with the assessments, apart from fatigue. If patients wish, they will get feedback about their performance and advice on post-operative language rehabilitation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patient group 1:

- Diagnosis of a radiologically presumed low-grade glioma; according to the judgement of radiologist, neurosurgeon or neurologist.
 - Location in the language dominant hemisphere (if unknown: right-handed and left-sided tumour)
 - Tumour is untreated
 - Planned to undergo awake brain surgery
 - In case of epilepsy, seizures under control with anti-epileptic drugs (less than six seizures in the previous year and on anti-epileptic monotherapy or polytherapy)
 - Between 18 and 75 years old;
- Patient group 2:
- Diagnosis of an intracranial, supratentorial meningioma
 - Location in the left hemisphere
 - Location: falcine and parasagittal meningiomas, when located at the skull base only sphenoid wing, and tentorial meningiomas when located supratentorially
 - Diameter > 3 cm
 - Tumour is untreated

- Planned to undergo brain surgery
- Presumed low-grade
- Language dominance in the left or right hemisphere
- In case of epilepsy, seizures under control with anti-epileptic drugs (less than six seizures in the previous year and on anti-epileptic monotherapy or polytherapy)
- Between 18 and 75 years old; Control group (comparable to the patient groups with respect to age, gender and education):
- right-handed
- between 18 and 75 years old

Exclusion criteria

For the patient groups:

- Non-native speaker of Dutch or insufficient command of the Dutch language
 - History of a medical, neurological or psychiatric condition known to affect language or cognitive functioning
 - (History of) substance abuse
 - Use of medication known to influence language or cognitive functioning, other than anti-epileptic drugs
 - Use of dexamethasone pre-operatively (peri-operatively according to local protocol is not an exclusion criterion)
 - Use of medication known to influence EEG, other than anti-epileptic drugs
 - Previous brain surgery or cranial radiation therapy;
- For the control group:
- Non-native speaker of Dutch or insufficient command of the Dutch language
 - History of medical, neurological or psychiatric condition known to affect language or cognitive functioning
 - (History of) substance abuse
 - Use of medication known to influence language or cognitive functioning
 - Use of medication known to influence EEG
 - Previous brain surgery or cranial radiation therapy

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 10-07-2016
Enrollment: 90
Type: Actual

Ethics review

Approved WMO
Date: 14-06-2016
Application type: First submission
Review commission: METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO
Date: 06-04-2017
Application type: Amendment
Review commission: METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO
Date: 28-11-2017
Application type: Amendment
Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28627
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL56362.042.16
Other	NTR-nummer: NTR5811
OMON	NL-OMON28627