

# Lesional epilepsy: the effects of surgical intervention on ictal onset zone and permissive neural networks

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Seizures (incl subtypes)
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON32984

### Source

ToetsingOnline

### Brief title

LESION

Lesional epilepsy and neural networks

### Condition

- Seizures (incl subtypes)
- Psychiatric disorders
- Nervous system, skull and spine therapeutic procedures

### Synonym

Epilepsy, seizures

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum

**Source(s) of monetary or material Support:** Nationaal Epilepsie Fonds

## Intervention

**Keyword:** Electrocorticography, epilepsy surgery, functional connectivity, graph analysis

## Outcome measures

### Primary outcome

The main study parameters are ECoG and MEG measures assessing functional connectivity and neuronal brain networks (clustering coefficient and path length), as well as the clinical measures of seizure frequency, epilepsy burden and cognition.

### Secondary outcome

This includes the MRI scans.

## Study description

### Background summary

Epilepsy is common in patients with circumscribed brain abnormalities, such as primary brain tumours and focal cortical dysplasias. In a substantial number of these patients, anti-epileptic drug treatment is ineffective. Patients with lesional epilepsy in whom no brain tumour is present will be referred to epilepsy surgery programs. The aim of these programs is to (1) identify and, subsequently, (2) remove the ictal zone. This leads to long-term seizure freedom in only 30-60% of patients.

Although in patients with brain tumours the primary aim of surgery is the removal of the tumour, it is increasingly acknowledged that resective surgery may also result in a decrease of seizure frequency. For both patient groups, improvement of outcome of epilepsy surgery will therefore be extremely relevant.

Electrocorticography (ECoG) and magnetoencephalography (MEG) are imaging techniques that are used for detection of seizure activity and epileptic source localization as well as assessment of functional connectivity and neural

network features throughout the brain. Recent research advances concerning functional connectivity and network properties of the brain have indicated that these techniques may be used for epileptic source localization and to investigate factors that determine the frequency of epileptic seizures. Application of these methods in candidates for epilepsy surgery may lead to more effective treatment and improvement of surgical outcome.

## **Study objective**

The primary objective of this study is to characterize functional brain networks in patients considered for (i) epilepsy surgery and (ii) tumour surgery with epilepsy surgery techniques. Characterization will be done preoperatively (MEG), during surgery (ECoG) and post surgery (MEG). At each stage, networks will be characterized using graph theoretical measures that are expected to be related to seizure proneness.

The secondary objectives of this study are: (1) To relate network properties at different stages to (i) seizure frequency, (ii) seizure burden, and (iii) cognition; (2) To develop a model to predict the effect of surgery on network changes and reduction of seizure burden.

## **Study design**

This is a longitudinal observational study.

## **Study burden and risks**

For patients, the burden associated with participation consists of a number of visits to the outpatients\* clinic for three MEG and MRI measurements, an ECoG and two neuropsychological screenings. It should be stressed that the ECoG, first MEG measurement as well as the first two MRI measurements are already part of routine practice in epilepsy patients. Furthermore, patients will be asked to keep a diary regarding the frequency and severity of epileptic seizures during the course of their disease. No health-related risks are involved in this study. In our view, the burden associated with participation is proportionate to the potential value of the research for patients suffering from epilepsy.

## **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

Inclusion criteria for pharmacoresistant epilepsy patients are (1) adult (>18 years) patients who (2) undergo resective surgical treatment at the VUmc regarding the Dutch Collaborative Epilepsy Surgery Program and (3) have given written informed consent. ;For brain tumour patients with epilepsy, inclusion criteria are (1) adult (\* 18 years) patients who (2) undergo resective surgical treatment of the tumour with epilepsy surgery techniques at the VUmc, (3) are suffering from epilepsy which was not pre-existent to the lesion and (4) have given written informed consent.

### Exclusion criteria

Exclusion criteria are (1) psychiatric disease or symptoms, (2) insufficient mastery of the Dutch language, (3) inability to communicate adequately.

## Study design

## Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

## Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 24-02-2010

Enrollment: 40

Type: Actual

## Ethics review

Approved WMO

Date: 21-07-2009

Application type: First submission

Review commission: METC Amsterdam UMC

## 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**

NL28447.029.09