# EEG-correlated functional MRI in the planning of presurgical intracranial EEG recordings in intractable focal epilepsy

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We want to address the following questions: How reliable is EEG-fMRI for epileptic source localization in difficult cases? Is EEG-fMRI able to replace intracranial EEG studies?

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

# **Summary**

### ID

NL-OMON31477

**Source** ToetsingOnline

**Brief title** EEG-fMRI in presurgical planning

### Condition

• Seizures (incl subtypes)

**Synonym** focal epilepsy

**Research involving** Human

### **Sponsors and support**

Primary sponsor: Academisch Medisch Centrum Source(s) of monetary or material Support: Ministerie van OC&W

### Intervention

Keyword: EEG, electrocorticography, epilepsy surgery, fMRI

### **Outcome measures**

#### **Primary outcome**

Cortical area (gyral location, surface delineation) of the epileptic source.

Difference (location, surface) between predicted source with EEG-fMRI and gold

standard (intracranial EEG).

#### Secondary outcome

Successful seizure outcome after 1 year postresection.

# **Study description**

#### **Background summary**

Epilepsy surgery is an effective treatment for patients with focal epilepsy who do not respond to anti-epileptic drugs. In the Netherlands, the National Dutch Taskforce on Epilepsy Surgery deals with all applications for epilepsy surgery, and consists of the 4 epilepsy centres and 3 academic hospitals. The UMC Utrecht is the oldest and still most important surgical centre. The Taskforce has a fixed diagnostic work-up for all patients and a central database that is supported by the UMC.

Essential to epilepsy surgery is the localization of the epileptic focus in the brain. In problematic cases, MRI, EEG findings and clinical seizure description do not converge and the localization of the focus is unclear. This often leads to further diagnostic tests (PET, ictal SPECT) and ultimately seizure monitoring using intracranial (implanted, subdural) electrodes. In spite of many technical advances, there still is a continuing need for such invasive recordings.

We recently introduced in the Netherlands a new technique of epileptic source localization, so-called EEG-correlated functional MRI (EEG-fMRI; see METC 04-276). The technique is based on detecting the BOLD effect (Blood Oxygen Level Dependent) by MRI. Differences in magnetic properties of oxygenated versus desoxygenated haemoglobin lead to signal intensity changes with (focal) brain activity. Therefore, an activated versus and inactivated state has to be defined. Only after averaging and statistical leveling the very small differences can be visualized. Until recently, fMRI paradigms consisted of repetitive tasks performed by a person at command. This cannot be used for epileptic activity which by definition occurs at random and can only be detected by EEG. Using the technical innovation that makes it possible to record EEG within the MRI scanner, it is possible to combine both and do off-line analysis with the occurrence of interictal spikes in the EEG as a trigger (activated state) for fMRI.

Using this technique we first investigated patients who had been rejected for epilepsy surgery (METC 05-250). This led to new insights in a number of these patients, and reconsideration of epilepsy surgery in a few of them. The current study is a logical step towards validation of EEG-fMRI as a source localizing tool, by comparing its results with the gold standard of intracranial EEG.

### Study objective

We want to address the following questions:

How reliable is EEG-fMRI for epileptic source localization in difficult cases? Is EEG-fMRI able to replace intracranial EEG studies?

#### Study design

All intracranial electrode implantations in the Netherlands take place in the UMC Utrecht, in about 10 patients a year.

All these patients with focal epilepsy who are implantation candidates will be asked to participate in the study and to undergo EEG-fMRI prior to implantation. Results from the EEG-fMRI study will be analyzed and a source localization will be provided, independent from the results of other tests. This source localization will be taken into account in the planning of the electrode placement.

After implantation, the position of the electrodes intracranially will be determined by coregistration of postimplantation CT with preoperative 3D T1 MRI cortical rendering. The location of the epileptic source(s) by the intracranial recordings will be projected on the 3D T1 MRI rendering, together with the predicted source(s) by EEG-fMRI.

Localization differences will be expressed in neurosurgical terms as gyral distance.

#### Study burden and risks

EEG-fMRI has been shown to be safe and of minor discomfort. The patient only needs to lie still. Discomfort from lying on the occipital electrodes can be relieved by a special vacuum pillow that also fixes head position. Noise during scanning is tempered by ear plugs.

EEG-fMRI might result in different hypotheses regarding the epileptic source, and thus to adaptation of the implantation strategy. In some cases, this will lead to a more extensive implantation. This is probably associated with a small increased risk of infection and hemorrhage, the two major complications of intracranial electrode implantations.

# Contacts

### Public

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# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

### Age

Adolescents (12-15 years) Adolescents (16-17 years) Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

all patients who are to undergo intracranial EEG evaluation (electrode implantation) in the UMCU, as part of the diagnostic protocol as decided by the National Dutch Taskforce on Epilepsy Surgery

# **Exclusion criteria**

A lack of interictal spiking in the standard EEG, defined as less than 10 spikes per hour. Contraindications for MRI, such as claustrofobia or presence of a pacemaker etc.

# Study design

### Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	04-08-2008
Enrollment:	20
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	26-02-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

# **Study registrations**

### Followed up by the following (possibly more current) registration

No registrations found.

5 - EEG-correlated functional MRI in the planning of presurgical intracranial EEG re ... 5-05-2025

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

No registrations found.

## In other registers

Register

ССМО

**ID** NL18352.041.07