Identification of epileptiform networks using functional MRI: model- vs data-driven approaches

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON38349

Source
ToetsingOnline

Brief title
Epileptiform Network Detection and Delineation (ENDD)

Condition

- Neurological disorders NEC

Synonym
Epilepsy, falling sickness

Research involving
Human

Sponsors and support

Primary sponsor: Epilepsiecentrum Kempenhaeghe
Source(s) of monetary or material Support: Europese Unie (ENIAC JU Grant). Het document van het Ministerie van Economische zaken (kenmerk ENI10000004U; project CSI;

projectnummer PNEI101007);waarin de verlening van de subsidie wordt besproken;kan te allen tijde opgevraagd worden bij de hoofdonderzoeker.

Intervention

Keyword: electroencephalography, epilepsy, functional MRI, networks

Outcome measures

Primary outcome

The primary study parameter is the similarity of the epileptic network(s)

obtained by the standard EEG-fMRI procedure and the data driven approach. The

gold standard used for validation are the results of the electroclinical

examination of the patient including the result of the EEG-Video examination.

Secondary outcome

A secondary study parameter is the confirmation or rejection of the

null-hypothesis of this study that the epileptiform network is similar before

and after medication withdrawal. In that case the data-driven approach might be

a valuable additional tool in the pre-operative work-up of patients with

localization related epilepsy, because it yields information that is not

dependent on EEG and the possible changes in (the amount of) epileptic activity

of the EEG.

Study description

Background summary

EEG-correlated functional MRI (EEG-fMRI) has been evaluated as a non-invasive technique for the pre-operative work-up. EEG-fMRI is unique, because it is able to visualize the activity of multifocal and deeply situated cortical areas. The results are promising: most studies report good concordance between activated BOLD areas and the presumed epileptiform focus. Despite many methodological

improvements, the sensitivity of the method ranges between 50 and 80%. The most important reason is an insufficient number of interictal epileptiform discharges (IEDs) during the limited time scope of the recording. To deal with this limitation, data-driven techniques that analyze the fMRI data without the use of EEG, might be an additional tool or even an alternative for EEG-fMRI. However, these techniques need to be validated before they can be used for clinical application.

Study objective

The primary objective of this study is to investigate whether a data-driven fMRI procedure enables the identification of the epileptiform network that can be used in the pre-operative work-up of patients with localization related epilepsy.

Study design

The first part of the study is a *proof-of-concept* study aimed at the methodological development of the data-driven fMRI technique. For that purpose, we will study patients with idiopathic generalized epilepsy (IGE) characterized by bilateral synchronized spike-and-wave discharges (SWDs) in the EEG which is typical for absence epilepsy, because the underlying networks of these discharges are reported to be robust and reproducible with EEG-fMRI and data-driven approaches. The EEG-fMRI data of these patients will be acquired within one recording session, while they are on maintenance doses of their habitual antiepileptic drugs. In the second phase (the clinical study), the added value of the data-driven approach will be evaluated by applying the two methods (EEG-fMRI and data-driven fMRI) to the simultaneously recorded EEG and fMRI of patients with localization related epilepsy who are candidates for epilepsy surgery (n=13). According to the standard clinical procedures the medication of these patients will be minimized during their pre-surgical video-EEG examination. EEG-fMRI data will be acquired before and at the end of the video-EEG session, such that we will obtain data of two situations: before and after medication withdrawal. For each situation, the data will be analyzed with the model- and data-driven approach.

Study burden and risks

Several safety issues are involved with the simultaneous recording of EEG and fMRI. Special MR-compatible EEG equipment is required that includes an EEG amplifier and EEG cap without ferrous materials, current limited resistors for each electrode on the cap and twisted electrode leads. We will use the equipment of MicroMed (Treviso, Italy) that has been used in a previous EEG-fMRI study as well (METC Utrecht, registration number 07-146/E). In addition, a second EEG cap is available, that has additional wired loops attached to the cap to record small movements of the electrode leads. Safety

tests were performed to test the equipment (for further information we refer to the safety report included in appendix A of the research protocol).
The additional risk of seizures occurring during scanning that may increase in case of medication withdrawal will be handled as usual by specially trained personnel: the scan will be aborted immediately and the safety of the patient will be assured.
All the patients who participate in this study will learn, especially, more about the underlying mechanisms or networks of their epilepsy. The results of the EEG-fMRI will, however, not influence the diagnosis and treatment on an individual basis, but the gain of knowledge certainly will be of importance for a better understanding and probably in the end a better surgical treatment of patients with complex partial epilepsy.

Contacts

Public
Epilepsiecentrum Kempenhaeghe

Sterkselseweg 65
Heeze 5591 VE
NL
Scientific
Epilepsiecentrum Kempenhaeghe

Sterkselseweg 65
Heeze 5591 VE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

The study will be divided into two phases related to two distinct patient groups, as described below.
1. proof-of-concept study for the methodological development (n <= 7):
- patients with idiopathic generalized epilepsy;
- older than 18 years;
- bilateral synchronous spike-and-wave discharges in the EEG;
- normal background EEG.;2. Clinical study to test the application of a data-driven approach in clinical practice (n <= 13)
- localization-related epilepsy determined from previous EEG recordings;
- candidate for pre-surgical video-EEG in Kempenhaeghe;
- older than 18 years;
- more than 15 epileptiform discharges per hour in scalp EEG, but less than 300 epileptiform discharges per hour (with medication).

Exclusion criteria

- suspicion of psychogenic non-epileptogenic seizures;
- suspicion of other neurological disorders;
- patients who cannot meet the mild physical or psychological criteria for prolonged MRI scanning;
- patients with very severe tonic-clonic seizures.
- patients who have a pacemaker or intracranial metals.
These exclusion criteria will be based on available clinical information of the patient and will be discussed with the neurologist of the patient. If the neurologist thinks that a patient will not be capable to participate in the study, the patient will not be included.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-12-2011
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	21-10-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	08-11-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	ID
CCMO	NL36415.041.11