

Development of a fMRI memory task for epilepsy surgery candidates

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The main object of this study is: Optimization of the face-name association task, such that this task can be used to examine the prediction of postoperative memory failure in preoperative patients with epilepsy. Sub Objectives:- Investigation and...

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

Summary

ID

NL-OMON35424

Source

ToetsingOnline

Brief title

Development fMRI memory task

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: Ministerie van OC&W

Intervention

Keyword: epilepsy, Face-name association task, functional MRI, memory

Outcome measures

Primary outcome

For each subject, lateralization index scores will be computed. These scores determine whether the provoked activations are bilateral.

Secondary outcome

Not applicable for this study.

Study description

Background summary

For patients with drug-resistant focal epilepsy neurosurgery could be a helpful treatment in terms of seizure reduction. However, these patients are at risk for disruption of the language or memory networks and deficits of these cognitive functions postoperatively. To minimize this risk, it is important to assess the lateralization of language and memory networks preoperatively. Currently, an invasive test, the Wada test, is used. Research is now focused on using the non-invasive method fMRI. fMRI language lateralization has already proven to be possible, but for memory this is more complicated. In the Netherlands there is no proper memory task available that can be used in fMRI to localize memory functions in patients with epilepsy.

The challenge is to develop a task that will provoke specific memory network activations, namely bilateral hippocampal activity. A promising fMRI memory task is the face-name association task. However, this task is currently used in research involving students and has to be adjusted to be suitable for patients.

Study objective

The main object of this study is:

Optimization of the face-name association task, such that this task can be used to examine the prediction of postoperative memory failure in preoperative patients with epilepsy.

Sub Objectives:

- Investigation and adaptation of the difficulty of the task, such that the participants under study perform well on the task
- Replication of the results of prior research (de Vogelaere et al., 2010) and provoke bilateral hippocampal activation
- Control for physiological processes using a photoplethysmogram (PPG)

The primary outcome is a fMRI memory task that can map the memory function bilaterally in healthy controls. Based on the outcome of this project, further research can be performed to assess the predictive value of memory fMRI in preoperative temporal lobe epilepsie (TLE) patients.

Study design

This is an observational study with healthy volunteers. The study is a feasibility study of the face-name association task in a clinical setting. The task will be adjusted and tested in the MRI on ten healthy volunteers, varying in age and education level. A lateralization index score will be computed, using significant Bold response strengths of the fMRI data. We anticipate that the fMRI memory task will subsequently be tested on epilepsy patients during a pre-surgical workup and that the results will be compared to the Wada test, currently in clinical use.

Study burden and risks

The healthy volunteers will undergo one MR scanning session (about 30 minutes in duration). There is no extra benefit for the participants themselves. The extra risk for the participants in this study are negligible.

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

- Age between 18 and 85 years
- Ability to give informed consent
- A medical history without epilepsy, other cerebral diseases, vascular problems, diabetes mellitus, hypertension and/or cerebral surgery
- No known structural lesions on MRI (and when found on MR during the research not further included)

Exclusion criteria

- Unable to undergo an MRI scan (e.g. pregnancy, claustrophobia, metal in body). This will be determined after the participants completed a MRI checklist.
- Insufficient mastery of the Dutch language
- Inability to communicate adequately
- A history of severe mental disease

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): 20-12-2011
Enrollment: 10
Type: Actual

Ethics review

Approved WMO
Date: 30-11-2011
Application type: First submission
Review commission: MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

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	NL38283.068.11