Intracranial registration in patients with refractory epilepsy, an integrative analysis of brain signals in response to sensory stimuli

Published: 03-09-2014
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To identify neuronal activation patterns in response to cognitive stimuli

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

Summary

ID

NL-OMON53069

Source
ToetsingOnline

Brief title
Cognitive mapping by intracranial registration

Condition

- Seizures (incl subtypes)

Synonym
Epilepsy - Convulsions

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cognitive mapping, Grid, High Frequency Activity

Outcome measures

Primary outcome

The main study parameter will be the topographic characterization of the neural activity during the processing of different sensory stimuli and the performance of attention as well as short-term memory tasks. The neural activity will be measured by ECoG and by functional magnetic resonance imaging (fMRI)

Secondary outcome

N.A.

Study description

Background summary

Cognitive stimuli processing is extremely important for humans. Neuronal activation patterns offer insight into cognitive processes. Most non-invasive methods have disadvantages of a limited temporal (fMRI) or spatial resolution (surface EEG). Registration with an intracranial grid electrode (ECoG) can overcome this problem. A combination of ECoG with fMRI can increase our understanding of cognitive processing in healthy controls and patients with epilepsy.

Study objective

To identify neuronal activation patterns in response to cognitive stimuli

Study design

Observational study

Study burden and risks

Participation will imply a test with repetitive stimulation of one of the

sensory modalities (vision, hearing etc.). For hearing: they listen to music, or phonemes or words passively, are will be asked to attend to certain characteristics in the stimuli. For vision: they will read letters or words and are asked to remember them and to recall them afterward. The test is harmless. The grid electrode will not be left longer in situ than clinically necessary. The fMRI at 7T (for patients and controls) carries no risks, though several precautions are taken.

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

Medically refractory epilepsy
Diagnostic workup up till that moment has not led to decline the patient for resective epilepsy surgery

A suspected (neo-)cortical seizure focus at the surface of the brain
Planned implantation of intracranial electrodes
Incapacitating epilepsy or seizures (no absolute minimal frequency)
Minimum age 18 years

Exclusion criteria

For patients
• Patients with (co-existent) psychogenic, non-epileptic attacks, or low IQ (below 70).
• (post-ictal) psychosis during the registration period will lead to exclusion from the research., For both patients as well as for controls:
1. Head injury with intracranial abnormalities (cerebral contusion)
2. Stroke (hemorrhagic or ischemic)
3. Metallic prostheses or pacemaker in the subject*s body or other contra indications for MRI. , For the healthy subjects only:
1. Any neurological or psychiatric disease
2. Use of medication affecting the central nervous system

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-03-2015
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	03-09-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-03-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC 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	NL47496.068.14