# Novel methods for function mapping and BCI in children

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

## Summary

### ID

NL-OMON53049

**Source**
ToetsingOnline

**Brief title**
Function mapping and BCI in children

### Condition

- Seizures (incl subtypes)

**Synonym**
Not applicable

**Research involving**
Human

### Sponsors and support

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

## Intervention

**Keyword:** BCI, Electrocorticography, Functional mapping, Functional MRI, Stereo-EEG

## Outcome measures

### Primary outcome

The end-points are described per primary objective: 1) Spatial match between fMRI/ECoG/stereo-EEG activation patterns and ECS results for different brain functions. 2) Mapping of target regions for BCI control and the ability of patients to achieve accurate BCI control.

### Secondary outcome

Not applicable

# Study description

### Background summary

Each year, a number of patients with refractory epilepsy are implanted with subdural strips and grids of electrodes (ECoG) or with depth electrodes (stereo-EEG) in order identify the epileptogenic focus and to determine whether this region can be surgically resected without loss of essential function. In the last years, a great portion of the scheduled patients are children, because they have a lot to gain by early resection of the epileptic focus (Spencer and Huh, 2008; Maehara et al., 2002). At the UMC, more than 70% of children treated are seizure free after 1 year. The neuronal signals measured using intracranial electrodes are of very high quality because of the direct contact between the neural tissue and the measuring electrodes, and are therefore highly suitable to answer a wide range of fundamental and applied neuroscientific questions, such as the mapping of brain functions and the development of assistive technology known as Brain-Computer Interfaces (BCIs). In the current proposal, we address these two topics in this population of patients, yielding two primary objectives.

### Study objective

In the current proposal, two primary objectives will be addressed. The first is to establish the spatial correspondence between fMRI, ECoG/stereo-EEG and ECS

for different brain functions in children. The second is to investigate the feasibility of an ECoG/stereo-EEG-BCI for children.

### Study design

Subjects will be included in an observational study.

### Study burden and risks

There are no known risks associated with fMRI acquisition. The technique does not require administration of any contrast agent or ionizing radiation. The fMRI procedure is painless. Slight discomfort may occur due to lying still with the head and part of the body confined in a tunnel-like device. There are no known risks associated with performing tasks during ECoG/stereo-EEG recordings. Implantation of electrodes does carry a risk which is taken into account in the clinical decision to operate. The present study does not add to that risk, as the grids are implanted purely for diagnostic purposes. The tasks are much like simple computer tasks or watching videos for children, and as such pose a minimal additional burden. No direct benefits are expected for the subjects of the current study. If results are positive, they are expected to form the basis for alternative, fast, and patient-friendly methods of functional mapping (as a manner to guide or eventually replace ECS), suitable for children of the same population (refractory epilepsy).

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

### Inclusion criteria

- Epilepsy patient (m/f) scheduled for implantation with either ECoG grids or stereo-EEG electrode strips
- Mental age 5-18 years

### Exclusion criteria

For fMRI:
- metal objects in the body that are not MRI compatible
- inability to lie still
-anxiety in scanner (evaluated by parent or after practise in mock scanner),
For ECoG and stereo-EEG: none

## Study design

### Design

**Study type:** Observational invasive

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Other |

### Recruitment

NL

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| Recruitment status: | Recruiting |

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| Start date (anticipated): | 12-11-2014 |
| Enrollment: | 80 |
| Type: | Actual |

## Ethics review

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|---|---|
| Approved WMO Date: | 21-05-2014 |
| Application type: | First submission |
| Review commission: | METC NedMec |
| Approved WMO Date: | 26-08-2016 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 24-04-2018 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 03-10-2018 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 30-01-2019 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 24-05-2019 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 02-05-2022 |
| Application type: | Amendment |
| Review commission: | METC NedMec |

# 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 | NL48022.041.14 |