Brain function in macro- and micro-networks - an ECoG/stereo-EEG and fMRI approach

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In the current proposal, we address four primary objectives:- Assess the precise relationship between hemodynamics and neuronal activity- Investigate the possibilities for high-dimensional brain decoding for ECoG(stereo-EEG)-BCI - Establish whether…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON56331

Source
ToetsingOnline

Brief title
Brain function in macro- and micro-networks

Condition

- Other condition

Synonym
NA

Health condition

primary objective 2: locked-in syndroom, primary objective 3: epilepsie

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: NWO,EU

Intervention

Keyword: Electrocorticography, fMRI, Networks, Stereo-EEG

Outcome measures

Primary outcome

The end-points are described per primary objective:

- Establishment and modeling (quantification) of the relationship between

hemodynamic signals measured with fMRI and underlying neuronal activation

patterns

- The ability of patients to achieve high-dimensional BCI control

- The correspondence between fMRI and ECS and between ECoG/stereo-EEG and ECS

- Function-selective measures of network dynamics, i.e. connectivity, causality

and spatiotemporal patterns

Secondary outcome

NA

Study description

Background summary

In the UMC Utrecht, each year about 10 epilepsy patients are implanted with subdural electrode grids (ECoG) or 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, such as motor and language. 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. In the current proposal, we address four primary objectives, all centred around two populations of patients: ECoG patients and stereo-EEG patients.

Study objective

In the current proposal, we address four primary objectives:
- Assess the precise relationship between hemodynamics and neuronal activity
- Investigate the possibilities for high-dimensional brain decoding for ECoG(stereo-EEG)-BCI
- Establish whether fMRI or ECoG/stereo-EEG frequency mapping can be a guide or an alternative to
ECS

- Elucidate the nature and functional correlate of interactions within and between regions involved in language and cognitive control

Study design

Subjects will be included in an observational study, with interventional components for some participants

Study burden and risks

There are no known risks associated with fMRI acquisition and the burden can be considered minimal (performing the fMRI localizer tasks may be slightly tiring). For patients from the ECoG population, during the clinical grid-implantation procedure, we will ask the neurosurgeon to implant an extra, high-density ECoG grid on a location that is clinically irrelevant, without changing the size or the location of the craniotomy. The added risk on post-implantation complications for participants due to this extra grid is estimated to be minimal (0.1% or 0.26%). High-density grids will not be offered to patients from the stereo-EEG population. There are no known risks associated with performing localizer or BCI experiments during ECoG/stereo-EEG recordings and the burden can be considered minimal. Electrocortical stimulation using (high-density) ECoG grids has proven to be safe and effective, and the risk of stimulation-induced seizures was found to be minimal.

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

- Epilepsy patient (m/f) scheduled for implantation with ECoG grids (for ECoG population) or stereo-EEG electrodes (for stereo-EEG population)
- 18 years or older

Exclusion criteria

There are no exclusion criteria for the current study. If a patient fulfils the inclusion criteria and gives informed consent, he/she can be included in the study. If a subject does not qualify for 3T and/or 7T fMRI (because of e.g. unremovable metals in the body), or is not willing to perform one or both of these scans, he / she will be asked to contribute to the ECoG or stereo-EEG part of the study. If a patient has already performed a clinical fMRI scan, or when clinical fMRI tasks are combined with research fMRI tasks in the same session, we will evaluate whether it is possible to use the data of the clinical scan/tasks for this research, to avoid having to perform a new fMRI scan, or a repetition of the same tasks, to minimize burden. Whether or not this is possible will depend on, among others, the task battery performed

clinically.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-10-2014
Enrollment:	117
Type:	Actual

Ethics review

Approved WMO Date:	11-09-2014
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	23-10-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	19-01-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	10-11-2017
Application type:	Amendment

Review commission:	METC NedMec
Approved WMO Date:	30-01-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	07-03-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-07-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	23-05-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-09-2023
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	NL50036.041.14