Acute electrocorticographic signal recording at the operating room

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

Summary

ID

NL-OMON48449

Source
ToetsingOnline

Brief title
Acute electrocorticographic signal recording

Condition

- Other condition

Synonym
NA

Health condition

NA, this is basic brain function research

Research involving
Human

Sponsors and support

Primary sponsor: Neurology & Neurosurgery
Source(s) of monetary or material Support: NIH

Intervention

Keyword: awake surgery, electrocorticography, fMRI, high density, optical imaging

Outcome measures

Primary outcome

The end-points per primary objective are as follows:

1) Achieving offline high-dimensional BCI control using high-density ECoG grids.

2) Establishing and modeling of the relationship between hemodynamic signals

measured with fMRI or optical imaging and the underlying neuronal activation

patterns measured with high-density ECoG.

Secondary outcome

NA

Study description

Background summary

Evidence from electrophysiological studies suggests that brain functions are a result of the connectivity between collections of neurons performing specific tasks, so-called neural ensembles or functional units. In the last decades, an increasing number of papers have been published on the neurophysiological underpinnings of human cognition and behavior at this level of detail, in particular using electrode grids (silicon sheets with embedded platinum discs) positioned under the dura in surgery patients. This technique, named electrocorticography or ECoG, has empowered the study of neurophysiological mechanisms and consequently improved the treatment of neurological and psychiatric brain disorders. At the UMC Utrecht, a combination of favorable factors such as 1) the excellent reputation in research on brain function involving implanted ECoG grids in the epilepsy surgery program, 2) the increasing number of surgeons at the UMC who are skilled in awake surgery (now

4), and 3) the increasing number of performed awake surgeries in the last years (50+ per year), has reinforced the fact that intraoperative recordings (awake and sleep) are a unique opportunity for research on brain function. In the last four years, we have conducted a pilot study with high-density ECoG grid recordings in epilepsy and tumor patients during awake surgeries (approved MREC 14-622). We introduced small high-density ECoG grids as a tool to study the detail of functional units. These grids promise to extract more detailed information from a smaller patch of the human cortex, potentially providing an advance in the field of human cognition and behaviour. In the pilot study we have determined whether awake surgery on patients with a brain tumor or other lesions allows for ECoG data collection of adequate quality to address research questions, which yielded exceptionally encouraging results. Optimal investigation of human brain functions at that level of detail is only feasible with highly resolved ECoG grids and is essential to increase the understanding about the human brain and can contribute to future improvement of neurotechnology devices, such as Brain Computer Interfaces (BCIs) and possibly in the long-run close-loop deep-brain stimulation systems.

Study objective

In the current study we expand on the knowledge previously learned in the pilot study and address a wider range of neuroscientific questions related to brain electrophysiological and hemodynamic responses. Because of the rarity and richness of this type of data we will combine multiple objectives in one study, such that we can efficiently address multiple research questions using one single setup. The main goal of this study is, therefore, to use high-density ECoG grids to address two main objectives:
1. Investigate the possibilities for high-dimensional brain decoding for ECoG-based Brain Computer Interfaces (BCIs);
2. Assess the precise relationship between hemodynamics and neuronal activity;

Study design

Subjects are included in an observational study, which includes intraoperative ECoG recordings with a high-density grid, intraoperative optical imaging and pre- or post-surgery structural and functional Magnetic Resonance Imaging (MRI, fMRI) scans.

Study burden and risks

During the surgery we will ask the neurosurgeon to temporarily position a high-density electrode grid on exposed or closely accessible brain surface, at a time that is convenient. ECoG grids are frequently used during epilepsy surgery and there are no known risks associated with their intraoperative use. All hardware used for the ECoG recordings is CE or MTKF certified and is safe. The ECoG measurements are not required for the surgery. There is no immediate

benefit to the participants. There are no known risks associated with intraoperative optical imaging and pre- or post-surgical MRI/fMRI acquisition. Intraoperative ECoG and/or optical recordings may slightly increase the duration of surgery (several minutes). Including all procedures, the burden can be considered minimal.*

Contacts

Public
Selecteer

Heidelberglaan 100
Utrecht 3584CX
NL
Scientific
Selecteer

Heidelberglaan 100
Utrecht 3584CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- age 18 years and higher and mentally competent;
- a clinical indication for resection of a tumor or other lesion (e.g. focus of epileptic seizures);
- a clinical indication for awake surgery (or if applicable, for a full asleep

procedure);

Exclusion criteria

- indication for longer than average (225 min) duration of the procedure (estimation by the neurosurgeon);
- the neurosurgeon decides that a certain patient is not eligible to participate in the study (e.g. for medical or surgical reasons);
- planned trepanation too far away for grid placement on a target location (evaluation by the neurosurgeon and researcher combined);
- reported function loss that prohibits the accurate performance of the required tasks;
Other exclusion criteria refer to specific parts of the study and do not affect the overall exclusion of the study. These are for example exclusion criteria for fMRI research, which include pregnancy, claustrophobia and presence of metals in the body

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):	18-01-2021
Enrollment:	84
Type:	Actual

Ethics review

Approved WMO

Date:	24-12-2019

Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	11-09-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	09-12-2020
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	NL70197.041.19