High-Density Intraoperative ECoG-A Pilot Study

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

Summary

ID

NL-OMON55585

Source
ToetsingOnline

Brief title
High-Density Intraoperative ECoG

Condition

- Other condition
- Structural brain disorders

Synonym
NA

Health condition

icm basaal hersenfunctie onderzoek

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: awake surgery, electrocorticography, fMRI, high density

Outcome measures

Primary outcome

Primary objective 1 - Recording functional HD-ECoG data

Principal parameter is the electrophysiological signal as measured from healthy tissue with the high-density electrode grid and dedicated HD-ECoG recording equipment. Key endpoint is the correlation between the brain activity recorded as such and an imposed task (R-squared value) and the comparison of the R-squared value with those obtained at the IEMU.

Primary objective 2 - Recording HD-ECoG data from epileptogenic tissue

Principal parameter is the electrophysiological signal as measured from epileptogenic tissue with the high-density electrode grid and dedicated HD-ECoG recording equipment in comparison to the routine low-density ECoG recording. Key endpoint is whether epileptiform activity is recorded with the same intensity, recognizability and extent.

Secondary outcome

NA

Study description

Background summary

With advancing analytical capabilities in mathematics and ever increasing computing power, measurements of electrical activity of the human brain are becoming increasingly valuable. An expanding number of papers are published on the neurophysiological underpinnings of human cognition and behaviour, using electrode grids (silicon sheets with embedded platinum discs) positioned under the dura in surgery patients. Many of these aim to elucidate mechanisms in order to improve treatment of neurological and psychiatric brain disorders. Evidence from electrophysiological studies suggests that brain functions are subserved by small collections of neurons performing the same specific tasks, so-called neural ensembles or functional units. Optimal investigation of human brain functions would be at that level of detail. Electrocorticography is already clinically used during epilepsy surgery and sometimes tumor surgery to find the epileptogenic brain tissue. Newly found electrical biomarkers for epilepsy, called high frequency oscillations, typically occur in small cortical areas and can be missed by large-scale recordings.

At the UMC Utrecht, research is conducted with high-density grids in epilepsy patients, as part of a larger ethics protocol (approved protocol 14-420). However, the duration of projects within that protocol is quite long due to a low volume of intracranially monitored eligible (ie adult) patients (6-8/year), with quite variable grid positions. Hence research questions with high-density grids are projected to last 3-6 years. This obviously is prohibitive. In the current protocol we want to explore the feasibility of obtaining high density electrocorticography (HD-ECoG) data in patients who undergo awake surgery, which takes place every week.

The UMC Utrecht has an excellent reputation in research on brain function and epillepsy involving implanted and/or intra-operative electrode grids (routine ECoG) in the epilepsy surgery program. Patients who undergo brain surgery for tumor or other (epileptogenic) laesion removal, undergo either an awake of sedated surgery, which can also include clinical registrations of epilepsy with routine low-density ECoG. Recent developments create the opportunity to address questions regarding the spatial detail of epileptogenic tissue and brain function in a more expedited fashion, with a different patient population. In 2013 the number of surgeons at the UMC who are skilled in awake surgery performed on patients with early stages of brain tumours, has doubled (now 4), and the number of performed awake surgeries has increased dramatically, to 50+ per year. Awake surgery offers a unique window of opportunity for research on epileptogenesis and brain function. During surgery, after removal of the tumour there is a period of 15-20 minutes in which the surgeon waits for bleeding to stop (haemostasis) while the patient is wide awake. In this period, an high density electrode grid can be placed on healthy cortex to collect ECoG data

while the patient performs one or two specific tasks. Moreover, during this type of surgery often routine intra-operative ECoG recordings are performed using standard clinical grids to localize the lesion*s associated epileptogenic tissue and tailor the resection. A HD-ECoG grid can be placed next to this routine ECoG grid to record in parallel high-resolution data of sick tissue (e.g. epileptogenic).

We will address two primary objectives related to performing HD-ECoG recordings, targeting the same patient population: patients with a tumor and/or epileptogenic laesion who will undergo brain surgery. There are two different surgical strategies in which we want to add our HD-ECoG recordings:
1.) obtain functional data - from healthy tissue - in people undergoing awake brain surgery for removal of brain tumors or other anomalies
2.) obtain data from epileptogenic tissue in people undergoing awake or sedated brain surgery in whom routine ECoG is recorded to delineate the epileptogenic cortex.

Study objective

We address two primary objectives: 1.) To determine whether (awake) surgery on patients with a brain tumor or epilepsy allows for HD-ECoG data collection of adequate quality to address research questions on brain function. In other words, we want to determine whether HD-ECoG studies on brain functions can be conducted during (awake) surgery. 2.) to develop and test HD-ECoG for better recognition of epileptogenic tissue and eventually replace the routinely used low-density grids.

Study design

Subjects are included in an observational pilot study with intra-operative functional ECoG recordings with a high-density grid on healthy (primary objective 1) and/or epileptogenic brain tissue (primary objective 2). An fMRI scan is performed to determine the grid position on the healthy cortex (primary objective 1 only).

Study burden and risks

There are no known risks associated with presurgical fMRI acquisition and the burden can be considered minimal (performing the fMRI localizer tasks may be slightly tiring). During the surgery we will ask the neurosurgeon to temporarily position a high-density electrode grid on exposed or accessible brain surface, at a time that is convenient. Grids are frequently used during epilepsy surgery and there are no known risks associated with their intraoperative use. All the ECoG equipment is CE certified and is safe. The ECoG measurements are not required for the surgery. There is no immediate benefit to the participants. Including all procedures, the burden can be

considered minimal.
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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 18 years and higher
- a clinical indication for resection of a tumor or other lesion (e.g. focus of epileptic seizures), with or without routine low-density ECoG recordings
- a clinical indication for awake (primary objective 1+ 2) or sedated surgery (during the initial, development phase of primary objective 1 + primary objective 2)

Exclusion criteria

- indication for longer than average (225 min) duration of the procedure (estimation by the neurosurgeon) (primary objective 1)
- 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) (primary objective 1)
- reported function loss in the domain of motor action and visual perception that may interfere with proper task execution (primary objective 1)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-09-2016
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	10-03-2015
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	22-03-2016
Application type:	Amendment

Review commission:	METC NedMec
Approved WMO Date:	26-08-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	20-12-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	25-04-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	30-12-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-04-2021
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	NL51088.041.14

Study results

Date completed:	01-04-2023
Results posted:	22-05-2023
Actual enrolment:	22

First publication
02-10-2019