Identification of signal propagation through the cortex using hd-EEG, validated with fMRI

Published: 09-06-2021
Last updated: 08-04-2024

The objective of this study is to validate the VBMEG algorithm by comparing hd-EEG with fMRI activity. If validated, it will be validated that the accuracy of the VBMEG algorithm is improved when fMRI is incorporated to the source reconstruction,...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Structural brain disorders
Study type	Observational non invasive

Summary

ID

NL-OMON52842

Source
ToetsingOnline

Brief title
Validation of signal propagation through cortex

Condition

- Structural brain disorders

Synonym
infaction; cerebral vascular accident

Research involving
Human

Sponsors and support

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

Intervention

Keyword: EEG, fMRI, Source, validation

Outcome measures

Primary outcome

The sources reconstructed with the VBMEG method will be compared to the fMRI activity map. The distance between sources will be calculated. If the distance is too far away from sources from the fMRI activity maps, the source will count as a false positive. When no source is located, while there should be a source, it is a false negative. The distance will be used in a Wilcoxon signed rank test comparing the fMRI activity map with the hd-EEG reconstructed sources.

Secondary outcome

n.a.

Study description

Background summary

The brain has always been of interest to us since we had a basic understanding of the human body. To understand the brain we need to know how the brain functions. Multiple devices are capable to do so. Two of the most use non-invasive devices are functional Magnetic Resonance Imaging (fMRI) and high density electroencephalography (hd-EEG). These devices enable us to find functional sources in the brain.
fMRI has a great spatial resolution (~2-3 mm). Its temporal resolution is rather low (5-6 seconds). Hd-EEG measures electric potentials generated by cortical areas. This data can be used to reconstruct the activity of sources in the cortex. This reconstruction is called the inverse problem. Hd-EEG has a high sampling frequency, but its spatial resolution is low (~5-6 mm). fMRI and hd-EEG are coupled by the metabolism of the neuron. If a neuron is more active, it requires more oxygen. This requires vascodilation in that area.
The inverse problem has seen many solutions over the years. These can be seperated into two categories, the dipole source algorithms and the distributed source algorithms. The inverse problem solvers can be regulated in multiple

ways. One of these inverse problem solvers is the Variational Bayesian Multimodal ElectroencephaloGraphy (VBMEG) algorithm.
A previous proof-of-principle study concluded that the VBMEG algorithm can track the dynamic information flow in the brain. The algorithm uses hd-EEG data as input. This data can be supplemented with MRI, dMRI and fMRI data to increase the accuracy of the algorithm.
The algorithm has been tested using simulations and in studies with visual parameters as input. What has not been validated is the comparison between hd-EEG source reconstruction using the VBMEG algorithm and fMRI activity maps. That is what this study is about.

Study objective

The objective of this study is to validate the VBMEG algorithm by comparing hd-EEG with fMRI activity. If validated, it will be validated that the accuracy of the VBMEG algorithm is improved when fMRI is incorporated to the source reconstruction, compared to the VBMEG algorithm without fMRI.

Study design

The study consists of two parts. The first part of the study is the fMRI part, in which a participant will take place in the MR scanner. A special MR compatible wrist manipulator robot (MRCWM) has been developed (Dyon Bode, 2017) which is able to apply a specific motion sequence perturbing a person*s wrist. The state of the brain is different due to the application of this motion compared to resting state. If the participant performs different tasks, the brain is put into different states. The activity can be compared for each state and Regions of Interest (ROI*s) can be identified.
The second part of the experiment has the participant use the MRCWM while recording EEG. The tasks performed are the same for fMRI as for EEG. Using the VBMEG algorithm, DTI and MRI, the sources and dynamic information flow between sources in the brain can be estimated. EEG source localization is compared to the fMRI results, validating the spatial accuracy of the VBMEG method. If validated, the fMRI is introduced to the VBMEG algorithm to validate that the accuracy is increased compared to EEG input alone.

Study burden and risks

Participating in the experiment requires participants to visit the Amsterdam UMC, location AMC once. The visit will last for about 6 hours for the fMRI and EEG experiments. The risks for the participant are low to non-existent. Below, the risks are defined which are related to the MR scanner, EEG scanner and the MRCWM.

Hd-EEG
There are no risks related to the hd-EEG recording. Hd-EEG recordings are safe

and require no burden on the subject, except fatigue due to a long time sitting still.

MR scan.
The MR scanner has a strong magnet, which results in multiple exclusion criteria for participants. These participants have implanted pacemaker, intracranial aneurysm clips, cochlear implants, certain prosthetic devices, implanted drug infusion pumps, neurostimulators, bone-growth stimulators, certain intrauterine contraceptive devices or any other type of iron-based metal implants. Other contraindicators are general metal objects such as shrapnel, bullets, as well as surgical pins, clips. There are other exclusion criteria. These are listed in chapter 5.4.

MR Compatible Wrist Manipulator robot (MRCWM)
The MRCWM can apply physically constrained maximum torques (1.5 Nm) and maximum angles (±67°), pre-set, such that the participant cannot be harmed. Due to the risk the connection poses between the MR incompatible part and the MR compatible part, the connection should remain intact as long as possible. Risks of the MRCWM are defined in the Medical Device Regulation (MDR) and are considered low

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

18 years or older
Has signed the informed consent
Capable of doing motion tasks using the MR compatible wrist manipulator (MRCWM)

Exclusion criteria

Pregnancy
Medication use
Mr incompatible metal bodies
Other contraindications in which a MR scan is not recommended (claustrophobia, obesity, etc.)
Incapability to give informed consent
Neurological disorders
Non-removeable metal objects
Abnormalities in the hand/wrist or prior surgery on the hand/wrist
History of alcohol or drug abuse

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-05-2022

Enrollment:	12
Type:	Actual

Medical products/devices used

Generic name:	MR Compatible Wrist Manipulator robot
Registration:	No

Ethics review

Approved WMO Date:	09-06-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-03-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL73208.018.20
Other	NL8783