Identification of signal propagation in the cortex using HD-EEG, validated by fMRI.

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Primary endpoint: Validate the VBMEG algorithm using hd-EEG source reconstruction compared to fMRI activity.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26190

Bron
Nationaal Trial Register

Verkorte titel
4DEEG

Aandoening

CVA, Parkinson, Epilepsy

Ondersteuning

Primaire sponsor: Technical University Delft
Overige ondersteuning: Technical University Delft

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Determine Pearson's correlation between HD-EEG source localization and fMRI.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: The brain has been of interest ever since we had a basic understanding of the human body. It processes information received from our senses, memorizes our past experiences, dictates what we should do and makes sure these commands are executed. The processing of this information can be done using non-invasive brain functional recording devices, such as fMRI and EEG. These devices have complementary characteristics in both the spatial and temporal domain. The functional brain recording with EEG is severely underdetermined problem, called the inverse problem. The solution has seen many solutions over the years. These solutions can be divided into two groups, the dipole model group and the distributed model group. The outcome for the dipole model group compared to EEG measurement is slightly different, while the outcome for the distributed model group is exactly the same as the EEG recording. These inverse solutions need regularization and this happens in a multitude of ways. One solution to the inverse problem is the VBMEG algorithm. A previous proof-of-principle study shown that the Variational Bayesian Multimodal EncephaloGraphy (VBMEG) algorithm can track the dynamic information flow in the brain following a stroke. The VBMEG algorithm is based on the hierarchical Bayesian model for source reconstruction using magnetoencephalography (MEG) or EEG and fMRI. The algorithm first calculates the inverse filter, which represents the currents flowing from the sources to the sensors. The sources are constructed using this inverse filter. The variance of the currents per source is estimated. This variance is not a given value and as such has a probability of becoming a value. The probability each variance is non-zero. The regularization matrix is estimated from the variance of currents. This matrix poses constraints on the inverse filter and hence, on the source location. From the covariance matrix, the free-energy is determined. If the free-energy has converged, the algorithm is done. If the free-energy has not converged, the regularization matrix is fed into the inverse filter and the process starts again.

This was done by combining EEG measurements with constraints derived from structural MRI analysis and DTI analysis of the white matter. However, this study only incorporated EEG measurements. The neurophysiological information gained from fMRI was not present. In this study, the VBMEG algorithm is validated by comparing the reconstructed EEG sources with the fMRI activity maps. If validated, the accuracy of the VBMEG algorithm can be enhanced with fMRI data as a prior. Hence, the second study parameter is validating that the accuracy of the VBMEG algorithm increases when fMRI data is used as a prior.

Objective: The objective of this study is to validate the VBMEG algorithm by comparing hd-EEG with fMRI activity.
Study design: 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 more different states. The activity can be compared for each state and activity maps can be

made. 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, dMRI, fMRI, EEG and MRI data, 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. This is an analytic observational cross-sectional study.

Study population: The study population will include 10 healthy subjects (males and females), between the age of 18 and 55 years.

Main study parameters/endpoints: Primary parameter: Validate the VBMEG algorithm using hd-EEG source reconstruction compared to fMRI activity.
Secondary parameters:
1. Verify that the VBMEG algorithm incorporating fMRI is more accurate than without fMRI.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness.
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 7.4.

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 accounted for and the advice of the SBI of the DHT of the AMC for the MRCWM states that the risks are deemed acceptable for this research.

Doel van het onderzoek

Primary endpoint: Validate the VBMEG algorithm using hd-EEG source reconstruction

compared to fMRI activity.

Onderzoeksopzet

1

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

18 years or older, signed informed consent, capable of doing motion tasks with the MRCWM

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Pregnancy, medication use, MR incompatible implanted metal bodies, other contraindications in which a MR scan is not recommended, icapability to give informed consent, neurological disorders, non-removable metal objects, abnormalities in hand/wrist or prior surgery on the hand/wrist, history of alcohol or drug abuse.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2021
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8783
Ander register	METC AMC : METC Nr: w20_325

Resultaten