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Project: „Objective EEG Bedside Assessment of Impaired Conscious Awareness in Epilepsy“

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Dear Participant,

to ensure the best medical care for all our patients, we consistently try to guarantee the highest quality standards concerning the diagnosis and treatment methods of different diseases. As a university hospital we are also a scientific research institution and are therefore actively engaged in research for the furtherance and improvement of the aforementioned methods.

We are currently conducting a study on patients suffering from epilepsy. The main objective of the study is a better comprehension of the occurring functional changes and their relation to clinical symptoms. In this context, we are interested in changes of consciousness and alertness in epilepsy patients. The investigation group is contributing to the development of a quantitative and objective marker for consciousness. As a participant, you will help us to detect differences between epilepsy patients and non-sufferers.

This study involves a neuropsychological assessment and diagnostic imaging with electroencephalography.

Procedure:

1. First, a preliminary discussion will take place to inform you about this study. Afterwards you will be asked to give your informed consent to participate. Finally, you will be invited to answer a questionnaire about demographic data such as age, educational background, handedness, and known psychiatric and neurological disorders.

In case of your personal suitability for the study, different neuropsychological tests will be performed. These tests register cognitive domains of interest, e.g. alertness, concentration and memory. Furthermore, we request you answer questionnaires about psychopathologies, sleep, consciousness, and quality of life. All the above mentioned examinations are protected by professional discretion and your data will be saved under a pseudonym only. These examinations will take about one hour.

2. Finally, we will ask you to participate in an electroencephalography (EEG) measurement. The EEG is a low risk procedure with rare complications. An EEG cap with 32 electrodes will be placed on your head to measure voltage fluctuations on the cerebral surface. This will provide information about communication between different brain areas. To measure EEG, a harmless gel electrolyte will be applied to the scalp. This gel can be easily washed from the hair and leaves no residue. After the EEG recordings you will have the opportunity to wash and dry your hair. Less than 1% of the healthy population show anomalies in EEG recordings, which can be interpreted as an increased risk for epileptic seizures. Therefore, it cannot be excluded that incidental findings will take place in the context of this study. For this reason, all measurements will be interpreted by a medical doctor. Any incidental findings do not necessarily fall into the category of disease. In case of incidental findings, you will receive written notice and a recommendation for an appointment in your neurological outpatient clinic for further information about the type and meaning of the incidental findings.

You may decide not to participate in this study and may interrupt the tests or measurements at any time during the study. Your participation helps us improve the diagnosis and treatment methods for our future patients. This study is subject to the provisions of data protection laws. All the data collected during the study will be saved under a pseudonym only, namely via encoding in numbers and letters. Given data will be used for scientific research only. You may withdraw your consent at any time with no explanation and without penalty.

In the case of clinically relevant findings we will contact you and optionally your treating physician.

We ask you kindly for your cooperation and thank you for efforts.

For any queries please contact:

Herrn PD Dr. med. Helmut Laufs, PhD

Klinik für Neurologie, UKSH, Campus Kiel

Christian-Albrechts-Universität zu Kiel

mail: h.laufs@neurologie.uni-kiel.de

Frau Inken Rothkirch, Dipl. Psych.

Klinik für Neurologie, UKSH, Campus Kiel

Christian-Albrechts-Universität zu Kiel

Telefon: 0049 431/ 500 23985

mail: l.toedt@neurologie.uni-kiel.de

Frau Gesine Hermann

Klinik für Neurologie, UKSH, Campus Kiel

Christian-Albrechts-Universität zu Kiel

Telefon: 0049 431/ 500 23985

Mobil: 0049 176/ 416 814 77

mail: gesine.hermann@uksh.de

Declaration of Consent

“Objective EEG Bed Side Assessment of Impaired Conscious Awareness in Epilepsy”

First name, Surname (participant)

I have been sufficiently informed in oral and written form about the objectives and methods, the possible risks and the benefits of the study. I have read the given information and understood its contents.

I had the opportunity to discuss this study with the doctor and ask questions. All my questions and concerns were answered and discussed to my satisfaction.

I agree that as part of the study, my personal data (name, date of birth, address, etc.) and my clinical data are recorded and anonymized (i.e. encrypted without any names given) to analyze and evaluate the results. All data collected in the course of the study will be treated confidentially in accordance with data protection laws.

I agree that the data will be analyzed scientifically and that results will be published anonymously. My participation in this study is voluntary and I know, that I am able to stop taking part in it at any time without having any detriments concerning my treatment as a patient.

At the time of revocation, at my request all collected data will be deleted, unless complete anonymization has taken place beforehand.

I hereby give my voluntary informed consent to participate in this study.

A copy of this declaration of consent and a copy of the participant's information was given to me.

place, date

signature participant

The participant was informed about the goal, meanings and any potential risks due to this study.

place, date

signature Medical Doctor and name in block letters