



REQUEST FOR PARTICIPATION IN THE RESEARCH PROJECT

EEG-based depth of anesthesia monitoring

This is a request for you to participate in a research project at the Department of Research and Development, Akutklinikken, Oslo University Hospital HF (Rikshospitalet).

You are selected because you are going to perform a scheduled operation under anesthesia.

What does the project entail?

We would like to consider a method for measuring how deep you sleep during anesthesia, which should be used in addition to all our usual measurements when you are in deep sleep, general anesthesia. Anything but this extra measurement will be exactly as we usually do in connection with the procedure you are going through and will not cause any discomfort.

Anesthesia, or general anesthesia, means that you are given strong sleeping medications and painkillers, so you are not conscious during the procedure. You are in anesthesia as long as the surgeon is operating. When the surgery is done, we will wake you from the anesthetic within minutes.

Based on gender, age, weight and height we can estimate how much anesthetic we have to give. We also use our experience as anesthesiologists / anesthesia nurses, when we regulate the depth of anesthesia, among other things based on how blood pressure and heart rate change.

Over the past 20 years, during major surgery, we have used devices that measure anesthetic depth with electrodes attached to the forehead. One of these devices, the Bispectral Index (BIS), automatically processes the electrical EEG signals from the brain and presents a number between 0 - 100. The number indicates the depth of sleep (100 = awake, 0 = very deep sleep) with some delay associated with the measurement itself. .

If too much anesthetic is given, sleep can be unnecessarily deep. This in turn can result in slower awakening and possibly some unrest after the anesthesia. Some studies have also shown that too much anesthetic affects our ability to perform more complex tasks in the days following anesthesia. We therefore also want to measure how the ability to solve tasks is changing. We do this by using an IPAD tool, where you do some tasks the day before the operation, and the same tasks 3 hours after the operation, and after 1 day.

Anesthesiologists /nurse- anesthetists have previously used the EEG signal to a limited extent to monitor anesthetic depth, although the EEG curves can provide a great deal of information about the state of the brain and how deep anesthesia is. The development of EEG-based methods for monitoring anesthesia depth continues and there is now a new generation of EEG devices that continuously measure brain activity with electrodes in the forehead and provide information on anesthesia depth without delay.

Therefore, the use of continuous EEG can further help us to control the depth of anesthesia and have the potential to become part of standard anesthesia equipment.

Everyone involved in this study receives the same type of anesthesia and is treated equally. We use both BIS and direct EEG to measure the depth of sleep in everyone. The difference will be whether or not the person managing the anesthesia will have access to the measurements. We place the patients in two random groups by lottery. In one group, we control the depth of sleep during anesthesia using EEG signals in addition to regular routine observation. In the second group, we control the anesthetic depth by means of regular routine observation of the patient.

Possible advantages and disadvantages.

The benefit of participating in such a study is that you will receive increased attention from the anesthesiologist and that anesthesia monitoring will be standardized and thorough no matter which group you are in. We believe that this type of study can help us dose anesthetics even more precisely in future. Anesthesiologists with long experience follow all patients thoroughly through the anesthesia and the anesthetic type is the same in everyone. After the anesthesia - before you leave home - someone from the research team will talk to you about how you experienced the anesthesia and experienced participating in this study.

If you do not choose to participate in the study, the treatment will otherwise be identical to whether you are in the study.

Voluntary participation and the opportunity to withdraw their consent.

Participation in the project is voluntary. If you wish to participate, sign the Declaration of Consent on the last page. You can, at any time, and without giving any reason, withdraw your consent. This will not have any consequences for your further treatment. If you withdraw from the project, you may be required to delete the collected information, unless the information has already been included in analyzes or used in scientific publications. If you later wish to resign or have questions about the project, you can contact PhD Fellow / Nurse anesthetist Anders Aasheim (Rikshospitalet, telephone 481 29 280, mail: uxanim@ous-hf.no), anesthesiologist Luis Romundstad (Rikshospitalet, telephone 994 26 414, e-mail: luirom@oushf.no), or Professor Leiv Arne Rosseland (Rikshospitalet, telephone 922 04 274, e-mail lrossela@ous-hf.no)

What happens to your information?

The information recorded about you should only be used as described for the purpose of the study. You have the right to access the information that is registered about you and the right to correct any errors in the information that is registered.

All information will be processed without a name and birth number or any other direct identifier information. A code links you to your information through a name list. The list that can link your name to the code will only be kept at the hospital and only personnel responsible for the study will have access to it.

Five years after the study is completed, ie by 2030, the name code will be destroyed so that the information about you is completely anonymous, also for the trial manager.

The project manager is responsible for the day-to-day running of the research project and that information about you is processed in a secure manner. Information about you will be completely anonymized or deleted within five years of the end of the project. It will not be possible to identify you in the results of the study when these are published.

Further information about the study can be found in Chapter A. Information on privacy, finance and insurance can be found in Chapter B. Statement of consent follows Chapter B.

Chapter A - detailed explanation of what the study entails.

Criteria for participation: We will include approx. 100 patients in the study. To be part of the study you need to be healthy outside the current illness, for which you will be operated. You must be above the age of 18 and be able to communicate in Norwegian or English.

Unfortunately, if you have epilepsy or other neurological illnesses, you cannot participate. We do not include pregnant and breast-feeding.

One of the study staff will talk to you before you are included in the study. You will then be able to answer the questions you have about the study. He or she will consider whether you meet the criteria to be included. It is important that you understand what the study entails and that you want to participate.

We want to investigate how your problem-solving skills change from before the operation, and 2 times afterwards, 3 hrs after surgery, and 24 hrs after surgery. The research leader will present some tasks to be solved on the IPAD the day before the operation. 1-2 days after the operation, a conversation will take place about how you experienced participation in the study, including whether you remember any dreams or other impressions from the time you were in the operating room.

The time spent will be the same in the two groups receiving anesthesia, that is, the time the patients are in anesthesia is equal.

Chapter B - Privacy, right of access and storage of material, finances and insurance.

Privacy. Information recorded about you in this study is general information such as age, gender, height and weight. We record information about the diseases you have and which medicines you use. From the operation, we record drug use, sleep depth (BIS / EEG), blood pressure information and heart rate. Before and after surgery, we test task-solving skills with the CANTAB-MCI IPad tool.

Representatives from the hospital (who sponsor the study), and supervisory authorities at home and abroad may be provided with study information and given access to relevant sections of your journal, in accordance with current laws and regulations related to privacy. The purpose is to check that the study information matches the corresponding information in your journal. Everyone who has access to information about you has a duty of confidentiality.

It may also be appropriate to publish a completely anonymized data set on the website of a scientific journal, which requires so-called "open access" to accept the publication of scientific results.

GDPR Requirement: Under the new Personal Data Act, the processing officer-Oslo University Hospital HF and project manager Luis Romundstad, have an independent responsibility for ensuring that the processing of your information has a legal basis. This project has legal basis in Article 6 (1a) and Article 9 (2a) of the EU Privacy Policy and your consent.

You can contact the Privacy Ombudsman at Oslo University Hospital:
Tor Åsmund Martinsen

Data Protection Officer

Email: toamar@ous-hf.no

Mobile 99 53 63 09 | Office 23 01 50 22

General questions and inquiries can be asked at personvern@ous-hf.no

You can also contact the Datatilsynet, if you have questions, or complain:

If you have experienced something that you believe is a violation of the privacy regulations, you can complain by sending a written request to the Datatilsynet's mailing address:

Datatilsynet

PO Box 458 Center

0105 Oslo

Storage of material. Research data is stored anonymously on the computers of Professor Leiv Arne Rosseland, PhD fellow Anders Aasheim and senior physician Luis Romundstad. Anonymous and de-identified data obtained from IPAD is stored in Cambridge Cognition (UK) 's secure data servers during the research period, and only the researchers in the study are granted access.

Economy. The study is funded by Oslo University Hospital HF

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Insurance. You who are part of the study are insured in accordance with the Patient Injury Act (cf. section 50 of the Health Insurance Act), and have ordinary rights as a patient at the hospital.

Information on the outcome of the study.

You who are part of the study have the right to get information about the outcome / result of the study when the data has been analyzed and the study published. If you are interested in this, contact one of the study staff.

Approval.

The project has been approved by the Regional Committee for Medical and Health Research Ethics, REK 32173 (14.11.2019), and by the privacy authorities.

Consent to participation in the study

I hereby declare that I will participate in the study

Signature of participant

date/place

Name of part (in CAPS)_____

I confirm to have given information concerning this project:

Name/date/role in the project