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University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research

Study Title for Participants: DBS Sedation Study

Formal Study Title: Effects of anesthesia drugs on neuronal activity in the basal ganglia and thalamus during deep brain stimulation electrode implantation surgery

Lead Researcher: Corey A. Amlong, MD (608) 263-8100

Where Lead Researcher works: University of Wisconsin-Madison, School of Medicine and Public Health, Department of Anesthesiology

_____ _____
Subject name MR#

Invitation

We invite you to take part in a research study about the effects of commonly used sedative drugs (propofol, remifentanil and dexmedetomidine) on the activity of cells in an area of the brain that is used as a target for deep brain stimulation (DBS) surgery. We are inviting you because you are already scheduled to have surgery to implant a DBS electrode as treatment for your condition. As part of the DBS surgery, a process called 'electrical mapping' of the brain is typically done to make sure that the electrode is placed in the best location. We hope to see if the sedative changes activity in the targeted brain areas.

The purpose of this consent and authorization form is to give you the information you need to decide whether to be in the study. It also explains how health information will be used for this study and requests your authorization (permission) to use your health information. Ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. Once we have answered all your questions, you can decide if you want to be in the study. This process is called "informed consent."

Why are we doing this study?

The purpose of this research study is to find out whether sedative drugs change brain cell activity in the target brain area during deep brain stimulation. This may help us learn how to use sedative drugs without affecting electrical mapping of the brain that takes place during DBS surgery. If we can identify a sedative drug that does not affect cell activity in the target region, we will be able to routinely use sedation during mapping and increase patient comfort during deep brain surgery.

Surgery for deep brain stimulation (DBS) is a procedure in which a pacemaker is placed in the brain to treat neurologic and psychiatric diseases. This surgery involves placing a stimulating electrode in specific brain areas (for each disease there is a specific brain target that is used to obtain optimal treatment results). In order to give the best treatment with the fewest side effects, the electrode needs to be placed in precisely the right location. In many medical centers, including at the University of Wisconsin Hospital and Clinics (UWHC), a process called 'electrophysiological mapping' is used during the surgery to find that precise location in the brain. This mapping is done by passing small electrodes through the target brain area to record activity of the cells in this region. The surgical team can tell where to place the electrode based on the type of cell activity they record.

Sedative drugs (sleeping medications) such as propofol, remifentanil and dexmedetomidine are often used in brain surgery where the patient needs to be awake during certain parts of the surgery, and in cases where light sedation may be used to keep the patients partially awake. But it is unclear if they change the activity in the target brain area during mapping for DBS electrode placement.

Some medical centers do not give patients any sedative drugs during DBS surgery because they are concerned that this medication might change the activity in the target area, which might make it harder to pinpoint the exact best location to place the electrode. Other medical centers use sedation, but stop it 10-15 minutes before the mapping procedure begins. This allows the patient to be awake, which makes the cell activity easier to identify, so it might be easier for the surgical team to tell what the best location is for implanting the electrode. Having no sedation during mapping can cause anxiety or discomfort in patients. At UWHC, we decide on the use of sedation before the mapping procedure based on the patient's condition and surgeon's preference. Some patients get sedation before the mapping procedure, and some patients do not get sedation. If sedation is used, it is stopped 10-15 minutes before the mapping procedure begins. After the mapping procedure is over, sedation may be started again for the remainder of the procedure.

This study is being done at the University of Wisconsin-Madison (UW-Madison). It is anticipated that 70-180 people will participate in this study at UW-Madison.

Funding for this study is provided by the UW-Madison Department of Anesthesiology.

What will I do in this study?

If you decide to participate in this research study, you will have your planned DBS surgery just like it usually is done at UW-Madison, except that, instead of being awake throughout the entire electrical mapping part of the surgery, you will be sedated for 30-40 minutes during the last mapping session. During the last mapping session of the surgery, we will sedate you using one of the three study sedatives (propofol, remifentanil or dexmedetomidine) and measure the effect of the study drug on the activity of the cells of the target area. This research-related sedation will add 30-40 minutes to the deep brain stimulation procedure. When we are done measuring the cell activity, we will return to the usual way that we do this surgery, which means you will be awake for the rest of the mapping, and you will receive standard of care sedation for the closure if your physician decides that sedation during closure is right for you.

How we will use your protected health information (PHI)

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

- Results of tests or procedures done as part of the study
- Things you tell the researchers about your health
- Information currently in your medical records as well as information added to your medical records during the course of this study. This information could include your medical history including your disease type and how long you've had it, your main symptoms, and medications that you take. We will get this information from your health care providers, such as University of Wisconsin Hospital and Clinics and UW Health.

How long will I be in this study?

You will be part of the study for about 30-40 minutes during your routine DBS surgery.

How is being in this study different from my regular health care?

People with your condition usually are brought out of sedation and are awake during the electrical mapping portion of the surgery. If you take part in this study, the main difference between your regular care and the study is that you will be sedated for 30-40 minutes during the last mapping session of the DBS surgery using one of the three study sedatives (propofol, remifentanil or dexmedetomidine) to measure the effect of the study drug on the activity of the cells of the target area.

This study is not part of your health care.

Do I have to be in the study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UW-Madison, UW Health or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Your authorization for researchers to use your protected health information (PHI) will last until the research study is done. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher, Dr. Corey Amlong, at Department of Anesthesiology, UW School of Medicine and Public Health, 600 Highland Avenue, B6/319 3272 CSC, Madison, WI 53792-3272.

What are the risks?

There is a risk that your information could become known to someone not involved in this study.

Participating in the study will lengthen the 3-5- hour surgery by 30-40 minutes. You will be sedated during the research procedures. The additional time that you will be sedated for the study may slightly increase the risks of the DBS implantation procedure.

The sedative drugs used for the study may cause slow heartbeat, low blood pressure, temporary high blood pressure, slow breathing, your breathing may stop temporarily, you may have airway obstruction, or a drop in your blood oxygen level. The drug remifentanil can cause muscle rigidity. There is a rare risk that propofol emulsion may get contaminated with bacteria and cause severe infection if improperly treated or stored.

Researchers may decide not to give the study sedative and to take you off the study if you have very low blood pressure or other issues that would put you at higher risk of side effects.

All the sedative drugs used in this study (propofol, remifentanil or dexmedetomidine) have been used successfully for this operation in regular clinical settings (outside of a research study). However, these drugs may change brain cell activity in different brain areas, which could make it harder for us to find the best spot to place the electrode. In order to reduce the chances that this interference will happen, we will give the drug only during the last mapping session, after the surgeon has found the target area for the electrode location. We will not move the electrode while you receive the drug. Then we will begin mapping again only after the drug effects are over.

Will being in this study help me in any way?

Being in this study will not help you directly. But your participation in the study may benefit other people in the future by helping us learn more about how to perform sedation without affecting the electrical mapping of the brain.

This study is not a substitute for your regular medical care. You should continue to see your regular medical providers.

Will being in this study cost me anything?

There will be no cost to you for any of the study activities or procedures. If you need treatment for side effects while you are on the study, you or your insurance will need to pay for this treatment.

Will I be paid or receive anything for being in this study?

We will not pay you to take part in this study or pay for any out of pocket expenses related to your participation, such as travel costs.

What happens if I am injured or get sick because of this study?

If you are injured or get sick because of this study, medical care is available to you through UW Health, your local provider, or emergency services, as it is to all sick or injured people. If it is an emergency, call 911 right away or go to the emergency room. For non-emergency medical problems, contact your regular health care provider. Here are some things you need to know if you get sick or are injured because of this research:

- If the sickness or injury requires medical care, the costs for the care will be billed to you or your insurance, just like any other medical costs.
- Your health insurance company may or may not pay for this care.
- UW-Madison and UW Health do not have a program to pay you if you get sick or are injured because of this study.
- By signing this consent form and taking part in this study, you are not giving up any legal rights you may have. You keep your legal rights to seek payment for care required because of a sickness or injury resulting from this study.

How will the researchers keep my research information confidential?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your health information, your name, address, phone number, and other information that can identify you. We will also store this information securely. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring this study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Who at UW-Madison can use my information?

- Members of the research team
- Offices and committees responsible for the oversight of research
- Personnel who schedule or perform medical tests or procedures, handle accounting and billing, or do other tasks related to this study

Who outside the UW-Madison may receive my information?

- The U.S. Food and Drug Administration (FDA)

Will information from this study go in my medical record?

Some of the information that we collect about you for this study will be put in your medical record. This includes information about the procedures performed in the hospital, such as the anesthesia used during the procedure, and measurements of the cell activity in the target area in your brain. Both you and your UW Health providers will be able to see these results.

Authorizing the research team to use your PHI means that we can release it only to the people or groups listed above, and only for the purposes described in this form. However, once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others.

Also, if ALL information that can identify you is removed from the health information collected in this study, then it is no longer PHI and this authorization will no longer limit how the remaining information can be used. This means the information could be used or shared for reasons other than the ones described in this form, such as a research study about another kind of disease. It also means that the information could be shared with researchers working at institutions that are not listed above.

What if I have questions?

If you have questions about this research, please contact the Lead Researcher, Dr. Corey Amlong, at (608) 263-8100. If you have any questions about your rights as a research subject or have complaints about the research study or study team, contact UW Health Patient Relations at 608-263-8009. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.

Agreement to participate in the research study

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study.

If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

_____

Printed Name of Subject

_____

Signature of Research Subject Date

_____

Signature of Person Obtaining Consent and Authorization Date

****You will receive a copy of this form****