Wake Forest School of Medicine

Departments of Anesthesiology and Psychiatry and Behavioral Medicine

EFFECTS OF PREMEDICATION WITH ALFENTANIL ON HEMODYNAMICS DURING AND IMMEDIATELY FOLLOWING ELECTROCONVULSIVE THERAPY

Informed Consent Form to Participate in Research
Quinn McCutchen, MD, Principal Investigator

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to participate in this research study because your medical doctor believes that electroconvulsive therapy (ECT) would be helpful in the treatment of your depression. This study is evaluating using a narcotic during your anesthesia for your ECT to see if your blood pressure and heart rate are more stable when it is used than when it is not used. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

This study is a joint effort of the Department of Anesthesiology and the Department of Psychiatry and Behavioral Medicine to investigate the potential effects of the anesthetic drug alfentanil in stabilizing heart rate and blood pressure during and immediately after ECT.
The goal of this study is to compare the effects (good and bad) of alfentanil with commonly-used medications that lower blood pressure and slow heart rate to see which is better. Alfentanil is a drug that is approved by the US Food and Drug Administration to be used in patients who are receiving general anesthesia or sedation when having surgery or procedures done.

In this study alfentanil will be compared to placebo. A placebo is a substance, like sugar water, that is not thought to have any effect on your disease or condition. In this study you will either receive the active study medication, alfentanil or placebo through your IV (a small catheter placed in a vein in your arm prior to your surgery to administer medications through). Placebos are used in research studies to see if the drug being studied really does have an effect. Neither you nor the investigator will know which group (alfentanil or placebo) you are assigned to.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

One hundred subjects will take part in this study at Wake Forest University Health Sciences.

WHAT IS INVOLVED IN THE STUDY?

You will be randomized into one of two study groups: Group 1-alfentanil or Group 2-placebo (no alfentanil). Randomization means that you are put into a group by chance. It is like flipping a

coin. As your course of treatment requires you to have more than one electroconvulsive therapy, you will receive a dose of study medication with each treatment. Therefore, you will have an equal number of ECT treatments where you receive alfentanil or placebo.

Neither you nor the investigator will know which group (alfentanil or placebo) you are assigned to. This is done so that a fair evaluation of results can be made. This information is available to the researchers if needed in an emergency. Regardless of whether you receive alfentanil or placebo, if necessary, other drugs may be given to keep your blood pressure and heart rate to as close to normal values as possible (as with any ECT treatment).

If you take part in this study you will be put to sleep (commonly called general anesthesia) as all ECT patients have whether they participate in this study or not. Ninety seconds before the ECT, you will receive the dose of the study medication in your IV. The ECT will be done as usual and following the treatment, you will wake up from the anesthesia. Your blood pressure will be measured and recorded at frequent intervals before, during, and after the ECT and heart rate and oxygen levels will be measured continuously throughout the procedure (this is normal for ECT). At discharge from the recovery area you will be evaluated by an anesthesia provider to see how you are doing prior to discharge.

How Long Will I Be in the Study?

You will be in the study for the number of ECT treatments your psychiatrist feels necessary to achieve the goal of improving your condition. You may have between 6-10 ECT treatments as part of planned treatment for your depression. You can stop participating in the study at any time during current or future ECT treatments.

What Are the Risks of the Study?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the treatment include: the risk of having ECT therapy and associated risks (you would have these risks if you have ECTs while not being in the study as well) and risks associated with receiving the drug alfentanil.
Alfentanil is a pain medication that is used very commonly during anesthesia for other procedures. Risks associated with the administration of alfentanil include the following: greater than 1% chance of occurring are nausea, vomiting, decreased or increased blood pressure, increased or decreased heart rate, chest stiffness, decreased breathing rate, blurred vision, dizziness, sleepiness; less than 1% chance of occurring are headache, confusion, shivering, itching, pain at injection site, and decreased breathing effort. If you are elderly, alfentanil may have a pronounced effect and may lead to severe decreased heart rate and decreased blood pressure. Also, in patients with impaired kidney lung, or liver function this medicine can have increased side effects such as severed decreased breathing effort and a decreased ability to metabolize the drug. However, this narcotic is administered by trained anesthesia personnel who have emergency equipment immediately available. The study medication is also given while you are asleep for your procedure with an anesthesiologist monitoring and assisting with breathing. You will also have in place continuous monitoring for your heart rate and your blood pressure, as is done routinely for this type of procedure. In addition, because this study involves receiving a placebo, there is a risk of receiving the placebo instead of alfentanil. This could possibly mean your blood pressure could become higher or heart rate faster during or after the ECT if you are

given the placebo. For all patients, we monitor blood pressure and heart rate very closely before, during, and after the ECT and if necessary, give medications to treat them. This is the same as if you were receiving ECT and are not in the study.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks. Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

Pregnant women are excluded from participating in this clinical research study. Due to unknown risks and potential harm to the unborn fetus, sexually active women of childbearing potential must use a reliable method of birth control while participating in this study. Reliable methods of birth control are: abstinence (not having sex), oral contraceptives, intrauterine device (IUD), DepoProvera, tubal ligation, or vasectomy of the partner (with confirmed negative sperm counts) in a monogamous relationship (same partner). An acceptable, although less reliable, method involves the careful use of condoms and spermicidal foam or gel and/or a cervical cap or sponge. We encourage you to discuss this issue further with your physicians if you have any questions.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be: a blood pressure and heart rate that is more stable during and immediately after ECT, fewer medications needed to treat high blood pressure or heart rate during and after ECT, fewer side effects from receiving medications to treat high blood pressure and heart rate, and improved satisfaction and less headache after ECT.

Because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive your ECT treatment. You should talk to your doctor about all the choices you have. If you choose not to participate in this study, you will receive the standard anesthesia medications and have your ECT treatments without being in this study.

WHAT ARE THE COSTS?

All study costs, including any study medications and procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility. Alfentanil is considered a study medication and you will not incur any additional charge should you receive this medication.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study. The findings from this research may result in a change in the care that is given to patients with conditions such as you have if it proves to be effective.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Wake Forest University Health Sciences Department of Anesthesiology. The researchers do not hold a direct financial interest in the product being studied.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted]

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Dr. Quinn McCutchen at [redacted] after hours).

What About My Health Information?

In this research study, any new information we collect from you] and/or [information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** vital signs such as blood pressure and heart rate, age, gender, medications given during ECT treatments, and information from you after the ECT regarding your feelings about the procedure.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the Institutional Review Board; representatives of Wake Forest University Health Sciences; representatives from government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study.
If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for an indeterminate period of time. This authorization does not expire any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center.

You can take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

WFU School of Medicine
Institutional Review Board
IRB Number:IRB00045800
Meeting Date Approved 7/1/2019
Version Valid Until: 6/30/2020

Dr. Quinn McCutchen
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study. By signing this form you give us permission to use your Protected Health Information for this study.

Laboratory test results and other medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A Wake Forest Baptist Medical Center medical record will be created for all study participants. Information about your participation in the study will be placed in your medical record, along with any routine medical test results that were obtained as part of 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 Web site at any time.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, your condition worsened, new information becomes available, you had an unexpected reaction, or because the entire study has been stopped.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WFU School of Medicine
Institutional Review Board
IRB Number:IRB00045800
Meeting Date Approved 7/1/2019
Version Valid Until: 6/30/2020

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Quinn McCutchen at [redacted] after hours).
The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted].
You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am/ pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am/ pm