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Wake Forest®
School of Medicine

Department of Internal Medicine, Section on Cardiovascular Medicine

COMPARISON OF BOLUS DOSING OF METHOHEXITAL AND PROPOFOL IN ELECTIVE DC CARDIOVERSION

Informed Consent Form to Participate in Research
Elijah Beaty, MD MPH, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to evaluate and compare the recovery time after a direct current cardioversion (DCCV) for patients sedated with either intravenous methohexital (Brevital) or intravenous propofol (Diprivan). You are invited to be in this study because you are about to undergo a direct current cardioversion (DCCV). Your participation in this research will involve only the one visit on the day of your procedure.

Participation in this study will also involve EKGs. All research studies involve some risks. A risk to this study that you should be aware of 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. There is no possibility that you may benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Elijah Beaty, MD MPH. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: Elijah Beaty at [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

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 take part in this study because you about to undergo a direct current cardioversion (DCCV). 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?

The purpose of this research study is to evaluate and compare the recovery time after a cardioversion in patients sedated with either intravenous methohexital (Brevital) or intravenous propofol (Diprivan).

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

One hundred fifty people at one research site will take part in this study. In order to identify the 150 subjects needed, we may need to screen as many as 200 because some people will not qualify to be included in the study.

WHAT IS INVOLVED IN THE STUDY?

You have a potential to be in this study because you are about to undergo a DCCV for your atrial arrhythmia. Atrial arrhythmias can be classified as atrial fibrillation, atrial flutter, and atrial tachycardia.

To make you comfortable for a cardioversion we use intravenous sedation medications. At Wake Forest Baptist Health, sedation is delivered by our anesthesiology group. Both methohexital and propofol are routinely used for sedation before cardioversion at this institution.

This study is a randomized trial. Should you choose to participate in this study, you will be randomized to receive sedation with one of these two study medications:

- Methohexital; or
- Propofol

Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an equal chance of being placed in any group.

This study is also "blinded". This means you will not be told which intravenous sedation medication you received until after your procedure.

Two standard 12-lead electrocardiograms (EKGs) will be obtained. One before sedation and one after recovery. An EKG measures the electrical activity of your heartbeat. EKG stickers will be placed on your chest for the EKG machine to measure this activity. EKG is standard practice during a procedure like your DCCV.

Following your DCCV, you will be asked to rate your recovery experience from and during the procedure on a scale provided to you by the study team.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study just for the day of your cardioversion.

You can stop participating at any time. If you decide to stop participating in the study we

encourage you to talk to the investigators or study staff first. There are no potential health or safety consequences from not participating in the study.

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 drugs we are studying include:

Methohexital:
Common side effects of methohexital include drowsiness, nausea, vomiting, chills, coughing, hiccups, muscle twitching; or mild skin rash or itching.

Propofol:
Common side effects of propofol include fast or slow heart rate, high or low blood pressure, rash and itching.

This study is comparing two approved methods for treating your condition. You will be randomly assigned to one of the two groups. It is possible that one treatment group may have a better response than the other. Therefore there is a risk that you may be assigned to a group that does not perform as well as its comparison.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. 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.

There also may be other risks 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.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future. It may allow us to select the safest and quickest method of sedation for a cardioversion.

WHAT OTHER CHOICES ARE THERE?

Your alternative is to not participate in this study. The selection of intravenous sedation for a cardioversion is up to the discretion of the attending anesthesiologist.

WHAT ARE THE COSTS?

Taking part in this study will not lead added costs to you or your insurance company. The costs of the ECG and the DCCV are part of the cardioversion procedure, independent of the study on sedation.

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.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Wake Forest Baptist Health's Department of Cardiovascular Medicine and is not funded.

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 Elijah Beaty at [redacted]

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**:** your name, medical record number, age, sex, race, height, weight, BMI, sodium, potassium, calcium, creatinine level, magnesium, medications, indication for cardioversion, results from your most recent echocardiogram and ECG.

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. Only the following people or organizations will be granted access to your Protected Health Information:

1) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research

2) Other people or laboratories providing services for this research project on behalf of Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center

3) Monitors, auditors, IRB or other regulatory agencies will be granted direct access to your original medical record for verification of clinical trial procedures or data, without violating your confidentiality and to the extent permitted by other applicable laws.

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 at least one year after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Elijah Beaty that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Elijah Beaty, MD MPH
[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 and North Carolina Baptist Hospital. 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 North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

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. You will still receive a cardioversion and appropriate follow up. 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, you failed to follow instructions, 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.

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, Elijah Beaty at [redacted].

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 (336) [redacted] or the Research Subject Advocate 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