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Title: Proof-of-Concept: A Device to Determine Return of Sensation After a Regional Anesthetic Block

Wake Forest®
School of Medicine

Informed Consent TO PARTICIPATE IN RESEARCH

Department of Anesthesiology

Proof-of-Concept: A Device to Determine Return of Sensation after a Regional Anesthetic Block.

Seiha Kim, D.O. Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to gain scientific knowledge that may help other people in the future. You are invited to be in this study because you will be having a spinal anesthetic block (injection of numbing medicine between the bones of the low back to numb the legs) for your surgery. Your participation in this research will involve being tested for your wearing off of the spinal anesthetic (return of sensation), and will last until numbness is gone.

Participation in this study will involve having a pad wrapped onto your non-surgical leg to detect when sensation returns (the numbness wears off) after your spinal anesthetic. The pad is part of an approved medical device, but which has been modified and will be used in an experimental way. The device will run cold water off and on through the pad wrapped to your leg, and you will be asked to press a stop button when you feel the pad gets cold. Nurses in the recovery area will also be testing return of sensation using a standard technique, and this will be compared to when you feel the cold in the pad. All research studies involve some risks. A risk to this study that you should be aware of is that the device will cool the skin, and if it is too cold for too long it could freeze the skin. In this study, the cooling will be turned on and off to minimize this risk. There is no direct benefit or cost to you for participating in the study, but the information could be used to help other patients in the future.

Your participation in this study is voluntary, and you do not have to participate in this study, or you may stop participating at any time. 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 Seiha Kim, D.O. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: **Seiha Kim, Email: sekim@wakehealth.edu Phone: [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 will be undergoing surgery with a spinal anesthetic. 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 determine whether a modification of an approved medical device will help tell when a spinal anesthetic has worn off. A spinal anesthetic can last a varying period of time depending on the medication and technique used, and also depending on patient factors. The ability to determine how long a spinal anesthetic lasts can be challenging and is not very precise. With the modified, experimental device that we have developed, we are hoping to make it easier and more accurate to determine when a spinal anesthetic has worn off.

The **Cold Rush Compact Cold Therapy System** is an approved medical device for cooling an area of the body (often a joint area) after exercise or surgery for many hours using cold water circulated through a pad on the body. It has been modified, and is therefore experimental, by adding a timer to turn the cooling on and off at regular intervals, a thermometer to check the temperature of the pad, and a stop switch you will press when you feel the pad gets cold. The stop switch will turn off the cold water flow. Since it has been modified, it has not been approved by the U.S. Food and Drug Administration (FDA). Drugs and devices that do not have approval by the FDA cannot be sold or prescribed by your physician.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

A total of fifteen (15) people at North Carolina Baptist Hospital or Davie Medical Center will complete the study.

WHAT IS INVOLVED IN THE STUDY?

If you take part in this study, before any anesthesia you will be tested for sensation to cold and to the prick of a toothpick on the thigh other than the leg you are having surgery on. If sensation is normal, then you will have the following tests and procedures:
You will undergo a spinal anesthetic (which would be normal for the surgery you will be having), and when you arrive in the recovery room the device pad will be wrapped onto the thigh of the leg your surgeon did NOT operate on. When you feel the pad get cold you should push the stop switch, and after that the device will stop cooling and will be removed from your leg. Whether or not you are in the study, you will be examined by a recovery room nurse, who will

also be testing when the numbness wears off after the spinal anesthetic every 30 minutes by using a toothpick on your body and leg to tell when you feel the prick from the toothpick. Recovery from your spinal and other factors are used to tell when you can be discharged to your room.

As part of this research study, a photograph or videotape may be done to demonstrate where the device was placed on your leg. You will not be identified in the photographs. You understand that you may request the filming be stopped at any time during the course of the research study. You can also withdraw your consent to use and disclose the photographs or videotape before it is used. You should also understand that you will not be able to inspect, review, or approve the photographs or videotape before they are used in this study.

Please choose one of the following regarding the use and disclosure of the photograph and videotape used in this research study:

_____ I would like the photographs and videotape of me to be destroyed once their use in this study is finished.

____ The photographs and videotapes of me can be kept for use in future studies provided they are kept secure and any future study will be reviewed by an IRB. I understand that I will not be able to inspect, review or approve their future use.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study until your spinal anesthetic has worn off enough, expected to usually be within 4 hours from when the spinal medication was injected. Your participation will end when the pad is removed from your leg.

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 to learn about any potential health or safety consequences.

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 device we are studying include:

The device used will circulate cold water through a contact pad that will be placed on your skin. The device is designed and approved to cool the skin, but if it is too cold for too long it could freeze the skin and you might not notice if you are numb. As approved, it is designed to cool continuously for many hours, but we have modified the device to turn off and on to cool for a shorter period of time (15minutes) and then stop cooling. This should minimize the risk to your skin.

There is a risk of transfer of germs to your non-surgical leg. The pad will be enclosed in a single use, sterile sleeve and is only applied to intact skin to minimize this risk.

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 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.

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.

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.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. If not in the study or if you choose later to discontinue participation, your recovery from spinal anesthesia will be tested in the usual fashion as described above.

WHAT ARE THE COSTS?

All study costs, including any study medications, equipment 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.

The cooling device is provided by the department of anesthesiology. Neither you nor your insurance company will be billed for the device.

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.

This research study may obtain data or information on the safety and/or effectiveness of the modified Cold Rush Compact Cold Therapy System; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

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 the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by The Department of Anesthesiology at Wake Forest Baptist Health**.** The researchers do not, however, hold a direct financial interest in the sponsor or 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 Seiha Kim, MD at [redacted] or [redacted] after hours.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any 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**:**

1. When the spinal anesthetic injection was completed
2. The dose and amount of numbing medicine used
3. Time to recovery from spinal anesthetic measured by your nurse
4. Time to recovery from spinal anesthetic measured by the device
5. Temperatures of cooling pad during the study
6. Name
7. Weight
8. Height
9. Medical record number
10. Patient study number

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 research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

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 the research project on behalf of Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center

3. The Regional Anesthesia and Acute Pain Management service team that may help to manage your pain should you stay in the hospital

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 unless there are photographs or recorded media which are identifiable. Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant 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 and will be kept for as long as a record of your medical information is kept by the medical center. 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 Seiha Kim, D.O. 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:

Seiha Kim, D.O.
[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 clinically relevant 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.

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 new information have been discovered, study has stopped or if you have an unexpected reaction. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

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, Seiha Kim DO at [redacted] or [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] 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