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OPIOID-FREE PAIN CONTROL REGIMEN FOLLOWING ROBOTIC RADICAL PROSTATECTOMY: A RANDOMIZED CONTROLLED TRIAL

Informed Consent Form to Participate in Research
Ashok Hemal, M.D., Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to study an opioid-free method of pain control versus the opioid treatment following robotic prostatectomy. You are invited to be in this study because you are receiving a prostatectomy. Your participation in this research will involve phone calls and will last from the time you provide your consent until up to 10 days after your surgery.

Participation in this study will involve you being randomly assigned as part of the opioid or opioid-free pain treatment groups. Each day after surgery while you are in the hospital, and between 7 and 10 days after surgery, you will be asked about side effects and to rate your pain using two questionnaires. If you are assigned to the opioid treatment group, you will complete a questionnaire about any opioid-related symptoms you may be feeling. You will also fill out 2 surveys before your surgery as part of your routine care. A non-opioid option for pain management is beneficial because opioid use may lead to increased risks for serious harm. Some risks of opioid use include developing opioid use disorder (opioid addiction or dependence), overdose, or falls. All research studies involve some risks. You may not 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. There may be other choices available to you. Some other choices may include opting out of the study. 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. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study please contact the Principal Investigator, Ashok Hemal, M.D., 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 Wake Forest University Health Sciences Research Subject Advocate 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 are receiving a prostatectomy. 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 compare the effects (good and bad) of an opioid-free treatment with commonly used opioids to see if they are equally good at treating pain. All medications in this study are FDA approved for the management of pain.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

100 people at 1 research site will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

Before surgery you will have blood taken for clinical purposes. You will have a physical exam, have your medical history recorded, and you will tell us about any medications you are taking. These things would happen if you were in the study or not.

Before the surgery, you will fill out two surveys about your health. These should take less than 10 minutes total to fill out and would be requested even if you did not participate in the study. Before surgery, on the day of surgery, the days following surgery while you are in the hospital, and at some point between 7-10 days after surgery, you will be asked to rate your pain from 0 to 10 using a visual pain scale, answer questions about your pain, complete a survey about specific side effects, tell us about any other side effects from the medicines you are directed to take for the study, and tell us about any other medicines you may be taking. This should take about 5-10 minutes/day. At some point between 2 and 4 days after your surgery, you will have a telephone call with our research staff to check if you are having any side effects as part of your routine care.

You will be randomized into one of the study groups described below. 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 either group. All patients will receive standard general anesthesia and receive local anesthesia medication (bupivacaine) during surgery per our surgical protocol.

Medication	Setting of Administration	Dosage
Opioid Group		
Oxycodone	*After surgery*	5 mg every 6 hours as needed for severe pain
Acetaminophen	*After surgery*	1000 mg by mouth 4 times daily (every 6 hours)
Opioid-Free Group		
Ketamine	*Before surgery / During surgery*	1.5 mg / kg IV
Ketorolac	*During surgery*	15 mg or 30 mg IV 3 times daily (every 8 hours)
Acetaminophen	*During surgery*	1 mg IV 4 times daily (every 6 hours)
Ketorolac	*After surgery*	15 mg IV 3 times daily (every 8 hours)
Acetaminophen	*After surgery*	1000 mg by mouth 4 times daily (every 6 hours)

Abbreviation Definitions: IV = intravenous (this means it is given in your vein); mg = milligram and kg = kilogram (milligrams and kilograms are measures of mass).

How Long Will I Be in the Study?

You will be in the study for up to 10 days from the time of surgery.

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.

What Are the Risks of the Study?

The study is comparing different approved methods for managing pain. 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. Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff.

As part of this study, you will be asked questions about your prostate, sexual health and pain. If we learn that you or someone else is in danger of harm, the study team is required to report that information to the proper authorities.

Opioid Group
If you are randomized into the opioid group, you will receive oxycodone and acetaminophen.

Risks of oxycodone

- Lightheadedness
- Dizziness
- Sleepiness

- Mental clouding
- Anxiety
- Mood changes
- Dependence
- Upset stomach
- Constipation
- Urinary retention
- Vomiting
- Rash
- Itchiness

Risks of acetaminophen
Some side effects may be serious including but not limited to the following allergic reactions:

- Red, peeling or blistering skin
- Rash
- Hives
- Itching
- Swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs
- Hoarseness
- Difficulty breathing or swallowing

Opioid-Free Group
If you are randomized into the opioid-free group, you will receive the following drugs: ketamine ketorolac, and acetaminophen. The risks for these drugs are described below.

Risks of ketamine

- Changes blood pressure (usually increases, but decreases may occur)
- Increased pulse rate
- Slowed and ineffective breathing
- Double vision
- Increased pressure in the eye
- Eyes moving rapidly or uncontrollably
- Anorexia
- Nausea
- Vomiting
- Pain at the injection site
- Allergic reaction
- Increased muscle tone, jerking movements
- Psychiatric events (anxiety, hallucinations)

Risks of ketorolac

- Headache
- Dizziness
- Drowsiness
- Diarrhea

- Constipation
- Gas
- Sores in the mouth
- Sweating
- Peptic ulcers
- Gastrointestinal bleeding
- Perforation of the stomach/intestines
- Renal failure/abnormal renal function

Some side effects that may be serious include the following:

- Fever
- Blisters
- Unexplained weight gain
- Shortness of breath or difficulty breathing
- Swelling in the abdomen, ankles, feet, or legs
- Yellowing of the skin or eyes
- Excessive tiredness
- Unusual bleeding or bruising
- Lack of energy
- Nausea
- Loss of appetite
- Pain in the upper right part of the stomach
- Flu-like symptoms
- Pale skin
- Fast heartbeat
- Cloudy, discolored, or bloody urine
- Back pain
- Difficult or painful urination

Risks of acetaminophen

Some side effects may be serious include the following allergic reactions:

- Red, peeling or blistering skin
- Rash
- Hives
- Itching
- Swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs
- Hoarseness
- Difficulty breathing or swallowing

As part of this study, you will be asked questions about your condition, side effects, and pain you may be feeling. Some of these questions may result in emotional distress.

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 to your health.

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. Instead of being in this study, you have the option to opt out of the study and may receive opioid as part of your pain control regimen following prostatectomy.

WHAT ARE THE COSTS?

Costs for your regular medical care, which are not related to this study, will be your own responsibility. All treatment, including surgery and pain medication, will be your own responsibility.

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 or permitted by law, or necessary to protect the safety of yourself or others.

Your 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 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?

Wake Forest University Health Sciences are sponsoring this study. The Wake Forest Baptist Comprehensive Cancer Center supports running the study. The sponsor is providing money or other support to the researchers to help conduct this study. The researchers do not 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?

Wake Forest University Baptist Medical Center maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of injuries or illnesses to some participants in certain research studies. 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. To the extent research coverage is not available, you or your insurance company may be charged for the costs of medical care. You may receive care at Wake Forest University Baptist Medical Center and/or Atrium Health.

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 Ashok Hemal, M.D. [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 demographic, preoperative, perioperative, and postoperative information.

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 the health care operations of Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities.

We will take steps 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 Atrium Health Facilities; 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.

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, videotapes, audiotapes or other recorded media which are identify you unless we you're your written authorization.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to your medical record for verification of clinical trial procedures or data to the extent permitted by other applicable laws. These monitors, auditors, and other individuals are also required to maintain the confidentiality of your protected health information.

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 six years 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. 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 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 Ashok Hemal, M.D. 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:

Ashok Hemal, M.D.
[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.

If you choose to participate in this study, your medical record at Atrium Health, Wake Forest University Health Sciences, or their respective affiliated entities 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. Authorization to access this part of the medical record will only be available to people who have a need to know this information in order to perform their job-related duties. If you are not a patient of these health care facilities, a medical record will be created for you anyway to provide access to this important information to providers 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.

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 Atrium Health, Wake Forest University Health Sciences, and/or their respective affiliated entities. These results and reports will be kept secure in compliance with applicable laws, with permission to access this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A medical record will be created for all study participants seen on-site and if a medical record doesn't already exist. Information about your participation in the study will be placed in the medical record, along with any routine medical test results that were obtained as part of this 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 of increased postoperative pain requiring medications or treatment beyond the scope of this study. Other circumstances includes instances where you medical team believes 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. 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, Ashok Hemal, M.D. 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 [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