Wake Forest®
School of Medicine

Department/Section of Urology

A Prospective Double Blind Randomized Control Trial Comparing the Standard-Of-Care (SOC) Prescription Analgesic to an Over-The-Counter (OTC) Analgesic Protocol In Managing Postoperative Pain After Ureteroscopy with Stent Placement

Informed Consent Form to Participate in Research
Jorge Gutierrez-Aceves, MD Principal Investigator

SUMMARY

You are invited to participate in a research pilot study. The purpose of this research is to determine if Over-The-Counter analgesia (pain relief medicine) works the same at relieving pain as the Standard of Care narcotic based analgesia that we normally prescribe for stent colic after ureteroscopy. You are invited to be in this study because you will be undergoing ureteroscopy. Your participation in this research will involve two clinic visits and last about 1 hour in total.

You will be undergoing ureteroscopy. Your participation in the study involves you taking a pain medication and completing a survey at clinic visit post operatively. You will track your use of the randomized analgesic prescribed to you the time between procedure and clinic visits. *Randomized* means that the choice of the analgesic given to you will be decided *randomly*, like by flipping a coin. All research studies involve some risks. A risk of this study that you should be aware of is not having your pain relieved adequately from the OTC medication, as well as, the unlikely possibility of becoming dependent upon the SOC narcotic medication. There is the possibility that you may benefit from participation in this study and that your pain will be well controlled from either medication.

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 deciding on the postoperative analgesia that you will be prescribed. 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 Dr. Jorge Gutierrez. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: [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 pilot 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 have kidney stones. 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 how well two medications work to control post-operative pain. One of the medications is normally prescribed for pain following ureteroscopy. The other medication is a common over-the-counter pain reliever.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

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

WHAT IS INVOLVED IN THE STUDY?

You will be randomized into one of two 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 each group.

During this study, you will be placed into a group that either is provided with the standard of care pain medication called Norco (a narcotic pain medication) or you will receive Ibuprofen (a non-steroidal pain medication that is available without a prescription) for post-operative pain management . Neither you nor the investigator or other people involved in the study will know which medication, you are receiving. 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.

No matter which medication you will receive, you will be evaluated in a standard fashion with blood work to measure your blood counts, electrolytes and kidney function as well as a urine culture. You will need to see the anesthesiologist prior to surgery to evaluate your heart and lungs for surgery. After surgery, we plan to send you home after spending about an hour in the surgery recovery room. You will then follow up in 1 week for removal of the stent in the office. You will be called at home post-operatively to assure adequate pain control. On return to the office, you will fill out a survey assessing pain control

Everyone in the study will undergo ureteroscopy. Ureteroscopy is a surgery where you will go to sleep in the operating room, and a camera will be placed into the bladder, then up into the kidney where your stone is located. Using a laser, the stone will be lasered into small pieces. The pieces will be removed using a small basket, and a small tube called a stent will be placed on the inside to drain the kidney. You will come back to clinic in about 1 week to have the stent removed. You will then follow up in about a month with a CT scan to check for any left over

stones.

How Long Will I Be in the Study?

You will be in the study for about 1 week until your follow up in the urology clinic.

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. Sudden withdrawal from the study could mean that you will have residual stones which could cause bleeding, pain, infection, kidney blockage, or kidney failure.

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.

There are also risks and side effects associated with Ibuprofen which include
-stomach pain, heartburn, nausea, vomiting, diarrhea, constipation, kidney damage, liver damage

There are also risks and side effects associated with Norco which include
- stomach pain, heartburn, nausea, vomiting, diarrhea, constipation, liver damage, slow breathing, tiny pupils, loss of consciousness, and opioid addiction/dependence

This study is comparing two approved methods for treating 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 and your pain relief may not be adequate.

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.

Reproductive Risks and other Issues to Participating in Research

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.

Pregnant women are excluded from participation in this study. Because some methods of birth control are not 100% reliable, a pregnancy test is required at least 10 days from your last normal menstrual period, if you are a sexually active woman of childbearing potential.

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 of choosing a surgical or non-surgical treatment option of your choice. These options include observation with medical expulsive therapy, ureteroscopy, mini percutaneous nephrolithotomy or shock wave lithotripsy.

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 about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:**
- age, medical comorbidities, body mass index, imaging results

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.

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.

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 Dr. Jorge Gutierrez-Aceves 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:

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 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.

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.

WHAT ARE THE COSTS?

There will be no added costs to your care for the medications. All procedures will be standard of care.

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 University Health Science. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study.

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. Jorge Gutierrez-Aceves at [redacted].

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 has changed or worsened, 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.

Identifiers might be removed from your identifiable private information or identifiable biospecimens and after such removal, your information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative

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. Jorge Gutierrez-Aceves 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].

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