Clinical Trial Evaluating the Efficiency of Holmium Laser Settings on Urinary Stones

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UNIVERSITY OF WISCONSIN-MADISON

Subject CONSENT to Participate in Research And AUTHORIZATION to Use and/or Disclose Identifiable Health information for Research

Title of the Study: Clinical Trial Evaluating the Efficiency of Holmium Laser Settings on Urinary Stones.

Principal Investigator: Stephen Y. Nakada, MD (phone: 608-263-1359)

Mailing Address: University of Wisconsin School of Medicine and Public Health, Department of Urology, Centennial Building, 1685 Highland Avenue, Madison, WI 53705

INVITATION

You are invited to participate in this research study comparing the effectiveness of using different laser energies to fragment stones with a holmium laser. You are invited to take part because you have urinary tract stones requiring surgical treatment. Approximately 48 individuals will participate in this study at the University of Wisconsin-Madison.

Your participation in this research study is voluntary. If you decide not to participate, the health care provided to you by the University of Wisconsin-Madison (UW-Madison) and its affiliates (the University of Wisconsin Hospital and Clinics and the University of Wisconsin Medical Foundation) will not be affected in any way.

A. WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of the research is to compare the effects of different laser energy on urinary stones in a clinical randomized prospective trial.

B. WHAT WILL MY PARTICIPATION INVOLVE?

If you decide to participate in this research you will be randomized (similar to the flip of a coin) to have your stones treated with a specific laser setting (0.2J&15Hz or 0.8J&15Hz) during your procedure. You will have an equal chance of being assigned to the higher or lower energy setting. All settings used have previously been used for many years at our institution and are used clinically to treat urinary stones. Your study participation will involve 1 clinic visit. The visit will involve the stone surgery, and will last approximately 5-6 hours, depending on the duration of the surgery.

For female participants, a urine pregnancy test will be performed prior to your surgery. Patients who are pregnant will not be allowed to participate. Your participation in this study is voluntary and will be complete at the conclusion of your procedure.

We will also collect the following information about you for this research study:

From your medical records, health records (such as x-rays), and/or billing records kept by

University of Wisconsin-Madison.

1. Operative time
2. Stone information
3. Size of stone fragments created
4. Size of residual fragment(s)
5. Postoperative complications
6. Laser information

C. ARE THERE ANY BENEFITS TO ME?

You are not expected to benefit directly from participating in this study. Your participation in this research study may benefit other people in the future by helping physicians learn more about the holmium laser settings used to fragment urinary stones including the most efficient settings to use for the treatment of urinary stones while minimizing any potential complications.

D. WILL I BE PAID FOR MY PARTICIPATION?

You will not be paid for your participation in this study.

E. ARE THERE ANY SIDE EFFECTS OR RISKS TO ME?

The holmium laser devices have been used since the 1990s, are currently approved for the treatment of urinary stones in humans, and are currently the standard method of fragmenting stones in the upper urinary tract. These devices have been used at our institution since 1995. Both of the laser settings to be used in the study are also used in routine clinical practice, and are not associated with significant complications. Clinical treatment with the laser for urinary stones is associated with rare risks of perforation of the urinary tract, bleeding, and stricture of the ureters. It is unknown whether the likelihood of these rare risks may differ based on the assignment to the higher or lower laser energy level. Assignment to the lower energy laser setting may result in the laser treatment taking a longer period of time to fragment stones. This may extend the duration of the surgery and anesthesia time for the procedure. This could result in an increase in the potential risks associated with anesthesia. The risks of anesthesia will be discussed with you as part of your standard clinical care. There is the potential for an unanticipated breach of confidentiality.

F. HOW WILL MY PRIVACY BE PROTECTED AND WHO WILL USE MY HEALTH INFORMATION?

The study team will code your study data and keep your private information confidential by storing it in a locked office on a password protected computer. Coding means we will assign a random study number to all of your information. Only the UW-Madison research staff will have access to the list linking your name and information. Your name will not appear in any publication of the results of this study. The US Food and Drug Administration may look at study records.

The information collected from you during this study and from your medical records will be used by the researchers and research staff of the UW-Madison and its affiliates (the University of Wisconsin Hospital and Clinics and the University of Wisconsin Medical Foundation) for this study.

It may also be shared with others at the UW-Madison and outside the UW-Madison.

Others at UW-Madison and its affiliates who may need to use your health information in the course of this research:

- UW-Madison regulatory and research oversight boards and offices
- Research support services staff at the UW-Madison and its affiliates

Others outside of UW-Madison and its affiliates who may receive your health information in the course of this research:

- U.S Food and Drug Administration (FDA)

People outside the UW-Madison and its affiliates who receive your health information may not be covered by privacy laws and may be able to share your health information with others without your permission. Usually when we share information from research studies with others outside the UW-Madison and its affiliates, it is not shared in a way that can identify an individual.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

G. ARE THERE ANY COSTS?

You or your insurance company will have to pay for all costs for medical care related to participation in this study, including co-payments and deductibles. You will have to pay for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may have to pay, you should contact your insurance company. If you do not have health insurance, you will have to pay all costs for your medical care just as you would if you did not take part in this study.

H. ARE THERE ANY ALTERNATIVES?

You do not have to participate in this study to receive treatment for your urinary tract stones. Alternatives to participating in this study would involve laser treatment with energy settings determined by the clinician's medical judgment rather than randomization. The study researchers can discuss your alternatives with you.

I. WILL I BE PAID FOR MY PARTICIPATING IN THE STUDY?

You will not be paid to take part in this study.

J. WILL THERE BE COMPENSATION FOR INJURY?

In the event that you are physically injured as a result of participating in this research, emergency care will be available. You will, however, be responsible for the charges for the emergency care. There is no commitment to provide any compensation for research-related injury. You should

realize, however, that you have not released this institution from liability for negligence. Please contact the investigator, Stephen Nakada, MD at 608-263-1359 if you are injured or for further information.

G. IS MY PERMISSION VOLUNTARY AND MAY I CHANGE MY MIND?

Your permission is voluntary. You do not have to sign this form and you may refuse to do so. If you refuse to sign this form, however, you cannot take part in this research study. If you do decide to participate, you may change your mind at any time without penalty or loss of benefits that you had prior to the study. You will be told of any new and significant findings which may affect your willingness to continue. Your decision of whether or not to participate in this study will not affect the quality of your medical care at this institution. You may completely withdraw from the study at any time.

IF YOU DECIDE NOT TO PARTICIPATE IN THIS STUDY OR IF YOU STOP WHILE THE STUDY IS UNDERWAY, THE HEALTH CARE YOU RECEIVE FROM THE UWMADISON AND ITS AFFILIATES WILL NOT BE AFFECTED IN ANY WAY.

K. HOW LONG WILL MY PERMISSION TO USE MY HEALTH INFORMATION LAST?

By signing this form, you are giving permission for your health information to be used by and shared with the individuals, companies, or institutions described in this form. Unless you withdraw your permission in writing to stop the use of your health information, there is no end date for its use for this research study. You may withdraw your permission at any time by writing to the person whose name is listed below:

Stephen Y. Nakada, MD University of Wisconsin School of Medicine and Public Health, Department of Urology, Centennial Building, 1685 Highland Avenue, Madison, WI 53705

Beginning on the date you withdraw your permission, no new information about you will be used. Any information that was shared before you withdrew your permission will continue to be used. If you withdraw your permission, you can no longer actively take part in this research study.

L. WHO SHOULD I CONTACT IF I HAVE QUESTIONS?

Please take as much time as you need to think over whether or not you wish to participate. If you have any questions about this study at any time, contact the Principal Investigator Stephen Y. Nakada, MD at 608-263-1359.

If you have any questions about your rights as a research subject or complaints about the research study that you could not resolve with the study team contact UWHC Patient Relations Representative at 608-263-8009.

AUTHORIZATION TO PARTICIPATE IN THIS STUDY AND PERMISSION TO USE AND/OR DISCLOSE MY HEALTH INFORMATION

I have read this consent and authorization form describing the research study procedures, risks, and benefits, what health information will be used, and how my health information will be used. I have had a chance to ask questions about the research study, including the use of my health information, and I have received answers to my questions. I agree to participate in this research study, and permit the researcher to use and share my health information as described above.

Name of Participant (please print): _____

Signature of Participant _____ Date _____

Signature of person obtaining consent and authorization: _____

Signature Date _____

YOU WILL RECEIVE A COPY OF THIS FORM AFTER SIGNING IT.