Identifiers:	NCT04505956
Unique Protocol ID:	Moses Ureteroscopy RCT
Brief Title:	A Comparison of Ureteroscopic Treatment of Nephrolithiasis With and Without Moses Technology

Consent

7/26/22

Study Title: PROSPECTIVE RANDOMIZED DOUBLE BLIND CLINICAL TRIAL TO COMPARE HOLMIUM LASER LITHOTRIPSY WITH AND WITHOUT MOSES LASER TECHNOLOGY FOR THE URETEROSCOPIC TREATMENT OF NEPHROLITHIASIS
Version Date: July 26th 2022
PI: Nicole Miller, MD

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key information about this study:
You are being asked to take part in this research study because you and your surgeon selected ureteroscopy with holmium laser lithotripsy for the surgical treatment of your kidney stone(s). Holmium laser energy is the preferred energy modality to break stones into fragments small enough to remove or pass spontaneously through the ureter. There is ongoing debate on the optimal means of laser stone fragmentation. Moses technology is the latest advancement in laser physics to theoretically improve laser energy delivery to the stone and reduce stone movement during fragmentation. To date, there are limited data proving the usefulness of the technology, and it is at least thought to be equivalent to previous laser technology with regards to safety and efficacy.

This is a multi-institutional study with total of accrual goal of 300 patients. Up to 100 patients will be enrolled at Vanderbilt University Medical Center. You will be randomly assigned to be treated with standard holmium laser settings with or without Moses technology. A temporary ureteral stent will be placed at the end of your surgery with the duration remaining at the discretion of your surgeon as is standard of care. Your participation in the study will last 6 weeks at which point you will follow-up in clinic with a CT abdomen/pelvis as is standard of care. The risks of participating in the study are the same as those for ureteroscopy offered outside the context of a clinical trial. You may benefit from being in the trial if you are assigned to the Moses group and it is found that the technology confers significant advantages over the standard laser settings.

Other treatment options would depend on your unique anatomy, kidney stone characteristics and medical problems you may have. This may include observation, extracorporeal shockwave lithotripsy, ureteroscopy, pyelolithotomy, and/or percutaneous nephrolithotomy at the discretion of your surgeon and as discussed in your pre-operative appointment. With regards to ureteroscopy, if you do not participate in the study, ureteroscopy will be performed with standard (non-Moses) holmium laser settings.

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You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:

The risks of participating in the study are the same as that of ureteroscopy offered as standard of care. These risks include pain, bleeding, infection, trauma to the urinary tract, and stricture development. Infection may be severe and life threatening in the form of sepsis requiring ICU hospitalization. Trauma to the urinary tract and/or stricture development may be severe and require future procedures. Loss of renal function may be seen as a result of trauma to the urinary tract, stricture development and any consequent procedures.

Risks that are not known:
There may be unknown or unanticipated adverse effects.

Good effects that might result from this study:
The benefits to science and humankind that might result from this study: To date, there are limited data proving the usefulness of the technology in reducing operative time, reducing stone movement during surgery, reducing surgeon workload, improving stone-free rates, etc. This study has the potential to determine if Moses technology is the new standard of care by demonstrating improvements in these outcomes.

Procedures to be followed:
As discussed above, you will be randomly assigned to be treated with standard Holmium laser settings with or without Moses technology. Neither you nor your surgeon will know if Moses technology was utilized until your follow-up appointment. Endoscopic video inside of your renal pelvis will be recorded to assess the degree of stone movement and confirm that the stone was adequately turned into dust. A temporary ureteral stent will be placed at the end of your surgery with the duration remaining at the discretion of your surgeon as is standard of care. Any subsequent hospitalization(s), blood draws, additional testing or additional procedures will be as clinically indicated and will not be for research purposes. You will follow-up in clinic 6 weeks after ureteroscopy with a CT of your abdomen/pelvis as is

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standard of care. The purpose of this imaging is to evaluate for any persistent stone, stone-free rate, development or persistence of hydronephrosis (obstruction), and the need for any additional procedures. Any complications during this 6 week period will be tracked.

Payments for your time spent taking part in this study or expenses:
None

Costs to you if you take part in this study:

There is no cost to you for taking part in this study.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact the study coordinator, **Amy Reed** at **(615) 322-2880** or the Principal Investigator, **Nicole Miller** at **(615) 322-2880**. If you cannot reach the research staff, please page the study doctor at **(615) 835-4968**.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
You may be taken out of the study if your anatomy complicates the assigned laser settings or intraoperatively, access is unobtainable in a retrograde fashion. Additionally, you will be withdrawn if staged ureteroscopy is deemed necessary intraoperatively (>1 ureteroscopy for the treatment of your stone burden).

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What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

Clinical Trials Registry:
A description of this clinical trial will be available on 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.

Confidentiality:

Data will be collected and stored within the secure database, REDCap (Research Electronic Data Capture). Only key study personal listed as the principal investigator, study coordinator and research-clinical roles will have access to the research information and video recordings. All investigators and support staff involved with collection or entry of clinical data are HIPAA certified through the CITI human subjects protection program and are current with regards to training. Since confidential information will be collected from the medical charts, we will not directly link personal identifiers with the data collected nor will we use personal identifiers in any reports, materials, or presentations that result from this study.

The principal investigator and study coordinator will be the only individuals with access to protected health information (PHI) within REDCap such as your medical record number. Within the database, you will be identified only by a unique study identification number. Recorded video will include only intracorporeal image frames of the renal pelvis. There will be no patient identifying information in the video clips such as external anatomy, PHI, date of surgery, etc. Recorded video clips will only be labeled by your unique study ID number. Video recordings will be stored in an encrypted drive and accessible only by key study personnel. De-identified video recordings will be sent to blinded reviewers using Secure File Transfer services.

When the study is concluded, all study personnel except for the principle investigator will be de-linked from REDCap. The principal investigator will maintain the information indefinitely in a password protected, encrypted database. All identifiers will be destroyed 4 years after the study initiation, or 2 years after data collection is complete, whichever is sooner. Video will be destroyed upon completion of data analysis except for select de-identified clips to be used for study presentation purposes.

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It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Study Results:
Data from the study as it pertains to your individual surgery can be shared with you once your participation in the study has been completed or terminated. Study results can be disclosed to you if you request once all data has been analyzed.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and

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contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

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Date _____ Signature of patient/volunteer _____

Consent obtained by:

Date _____ Signature _____

Printed Name and Title _____

Time: _____