Superpulsed Thulium Fiber Laser VS. Pulse Modulated High Power Holmium:YAG Laser For Retrograde Intrarenal Surgery

PI: Mantu Gupta, MD

NCT05808257

Document Date: 11/7/2023

STUDY INFORMATION:

Study Title: Superpulsed Thulium Fiber Laser VS. Pulse Modulated High Power Holmium:YAG Laser For Retrograde Intrarenal Surgery

Study site(s): Mount Sinai West

Lead Researcher (Principal Investigator): Mantu Gupta, MD

Physical Address: 425 W. 59th Street, Suite 4F. New York, NY 10019

Mailing Address: 425 W. 59th Street, Suite 4F. New York, NY 10019

Phone: 212-241-1272

SUMMARY OF THIS RESEARCH STUDY:

This document explains a research study you might be interested in joining. Participation in the study is voluntary. You can agree to join or not. Your decision will not limit your ability to receive care at Mount Sinai. You should only agree to take part if you understand the study and if all of your questions about the research study are answered. If you do join the study, the research team must share any new information with you that may change your mind about taking part.

The purpose of this research study is to compare two laser systems used to break up kidney stones during surgery to see if there are any differences in how they perform.

If you choose to take part, there will be no additional visits required outside of the standard of care, and there is only a minimal change from your regular care. When you undergo kidney stone surgery, a laser is used to break apart your kidney or ureteral stones. This laser can either be a Thulium Laser or a Hol:YAG laser. Both lasers use similar technologies, are FDA approved, and are used interchangeably for kidney stone surgery for your regular care at Mount Sinai. There is nothing investigational about either laser. For this research study, we will deliberately be using one laser over another during your surgery to see if the type of laser used plays a role in outcomes during and after surgery. There are no costs to participating in this study, and you will not be paid to participate in this study.

If you choose to take part, the main risks to you are the same risks associated with kidney stone surgery. Your doctor will explain these risks to you. There is also a risk of loss of private information, but there are procedures in place to minimize this risk.

You will not benefit directly from taking part in this research. Instead of taking part in this research, you may have your kidney stone removal procedure without being a part of the study. If you are interested in learning more about this study, please continue to read below.

STUDY PARTICIPATION:

You may qualify to take part in this research study because you have a urinary tract stone in the kidney and are scheduled for a ureteroscopy (URS) to remove the stone.

Your participation in this research study is expected to last three months.

There are 82 people expected to take part in this research study at Mount Sinai West.

Funds for conducting this research study are provided by Mount Sinai.

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 website at any time.

DESCRIPTION OF WHAT IS INVOLVED:

If you agree to take part in this research study, here is what may be involved:

During your initial consultation with Dr. Gupta or Dr. Atallah at Mount Sinai West, you will be asked to read this informed consent form and give us permission to collect data from your medical records about this procedure. You will be given time to ask questions about the study to your study doctor. After your questions have been answered and you understand the information in the consent form, you may choose to participate in this study by signing and dating this form. Instead of signing the form today, you may take the form home with you if you would like additional time to think about participation. If you choose to participate, you will receive a copy of this signed and dated form for your records. Your doctor will see if you are a good fit for this study by asking you a series of questions about your medical history. Your doctor will also determine the procedure that you will need based on your medical history.

On the day of surgery, you will undergo surgery with Dr. Gupta as planned according to the standard of care. You will randomly be assigned to one of two groups based on the type of laser that will be used to treat your stones:

1. Holmium:Yag (Moses) laser
2. Thulium (Soltive) laser

Both lasers are approved by the FDA and are both used interchangeably as a standard of care option to break apart kidney stones.

After the procedure (which takes 1-2 hours), you may be discharged on the day of your procedure or you may be required to stay in the hospital for a short period of time. 2-3 months after the procedure, you will obtain a CT scan to check if your kidney has any residual swelling and to determine if there is any residual stone burden, and you will follow up with your doctor to discuss the results. This CT scan is done according to the standard of care and would occur at this same time point regardless of your participation in the study.

Your study involvement is complete once the follow up appointment is completed.

Randomization

No one, not you, or anyone from your medical team or from the research team will be able to choose what group you are assigned to or what laser is used during your surgery. It will be by chance, like flipping a coin. You will have an equal chance of each laser system being used.

USE OF YOUR DATA AND/OR SAMPLES:

In addition to being used to complete this research study, your personal information (such as, name, address, date of birth, social security number), study data, and samples (blood, tissue, urine, saliva, or any other body matter.) may also be used and shared for additional (future) research. Before anything is shared, all of your identifying personal information will be removed and it will be replaced with a code. Researchers are not planning on giving you the details of any of this future research nor the results. That means that a research project might be done that you would not consent to if provided with the details of that research project. If you do not want any future research to be done with your data and/or samples, even with your identity removed, please do not sign this consent form or take part in the study.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study, you will be responsible for the following things:

- Follow the directions of the study doctor and study staff.
- Allow us to follow your care for 3 months and access your medical records.
- Obtain a CT scan 2-3 months after surgery (A CT scan would occur at this time point regardless of study participation)
- Follow up with your study doctor 2-3 months after surgery

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will not be paid for taking part in this study. Being in this study will not cost you anything extra.

POSSIBLE BENEFITS:

This study is not designed to benefit you personally. However, possible future benefits to others include providing valuable data on the effectiveness of kidney stone surgery.

POSSIBLE RISKS AND DISCOMFORTS:

- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.
- There are risks to taking part in any research study. You should discuss these with the study doctor and/or your regular doctor. There also may be other risks, discomforts or bad reactions that we cannot predict. Known risks for this study include the same risks associated with any standard of care ureteroscopy performed under general anesthesia. Your study doctor will talk to you about all of the risks. Known risks may include, but are not limited to bleeding around the kidney, infection, blockage of the ureters by stone fragments, difficulty in urinating, blood in the urine, pain from the stent, bladder spasms, abdominal pain which may be lower or to the back and stone fragments left which may require another lithotripsy.
- The study doctor is an investigator in this study and is interested both in your medical care and in the outcome of this study. Before you sign up for this study or at any time during the study, you may discuss your care with another doctor who is not associated with this research project. You are not under any obligation to take part in the study.
- Breach of Confidentiality: There is a risk that someone could get access to the data we have stored about you. If those data suggest something serious about your health, it could be misused. For example, it could make it harder for you to get or to keep a job or insurance. We believe the chance that these things will happen is very small; however, we cannot make guarantees.
- Group Risks - Although your name will not be given to researchers, basic information such as your race, ethnic group, and sex may be shared. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes or discrimination.

OTHER OPTIONS TO CONSIDER:

You may decide not to take part in this research study. If you decide not to take part, this will not affect the clinical care you receive at Mount Sinai. The choice is totally up to you.

Instead of being in this research study, you may have a ureteroscopy described in this study without being a part of research.

IN CASE OF INJURY DURING THIS RESEARCH STUDY

If you are injured or made sick from taking part in this research study, you will get medical care. Generally, it will be billed to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, copayments, and coinsurance. This does not prevent you from seeking payment for injury related to malpractice or negligence. You can contact the Lead Researcher for more information.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this study at any time. No matter what you choose, your care and benefits through Mount Sinai will not be negatively impacted.

If you decide to stop being in the study, please contact the Lead Researcher or the research staff.

You may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page. Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you decide you don't want your data and/or samples to be used for research anymore, you can contact the researcher and ask to have your data and/or samples withdrawn or labeled so that they will not to be used in additional projects or shared. If your data and/or samples have already been shared with researchers, those researchers will be asked to stop using them. However, if any data and/or samples have already been shared without your identity or a linking code, it won't be possible to retrieve them. Data and/or samples that have already been used will not be affected by your decision. If your data and/or samples have already been deposited in an external repository, the study team will request that your data and/or samples be removed.

Withdrawal without your consent: The Lead Researcher, the funder or Mount Sinai may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the research team have not been followed, the Lead Researcher believes it is in your best interest, or for any other reason. If data and/or samples have been stored as part of the research study, they too can be destroyed without your consent.

CONTACT INFORMATION:

If you have any questions, concerns or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Lead Researcher at phone number 212-241-1272.

DISCLOSURE OF FINANCIAL INTERESTS:

Researchers sometimes get paid for consulting or doing work for companies that produce drugs, biologics or medical devices. If you have questions regarding industry relationships, you are encouraged to talk to the Lead Researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As part of this study, some of your private and/or protected health information will be obtained, used, and shared with your permission. There is a Federal Health Insurance Portability and Accountability Act (HIPAA) that makes sure this is done correctly and safely.

What is protected health information (PHI)?
PHI is the combination of two things:

1. PHI contains information that identifies you. It will be used to contact you and link you to your health information, like name, date of birth, medical record number, and address.
2. PHI also contains health information, including information about your mental and physical health from your visits to doctors or hospitals, or from study visits.

Every time you visit a hospital or your doctor, PHI is created and recorded in your medical record by your healthcare providers. In the same way, the PHI created as part of this study will be linked to who you are and your medical information.

What PHI is collected and used in this research study, and might also be shared with others?

As part of this study, the research team at the hospital(s) involved in the research will collect your name, address, telephone number, dates directly related to the individual (birth, admission, discharge, date of death, etc.), e-mail address, and medical records number.

During the study, the researchers will gather information by:

- Reviewing and/or taking your medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- Doing a physical examination that generally also includes blood pressure reading, heart rate, breathing rate, and temperature.
- Completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.

Why is your PHI being used?
Researchers need the information that identifies you so they can contact you during the study. They need your health information and the results of any tests and procedures being collected as part of this study to answer the questions posed in the study. The purpose of the study is discussed earlier in this consent form. Before researchers analyze the data, they remove any information that would let others know who you are or that you took part in the study. If researchers publish or present study results at scientific meetings, lectures, or other events, their presentations would not include any information that would let others know who you are, unless you give separate permission to do so.

The Lead Researcher may also use and share the results of these tests and procedures with other healthcare providers at Mount Sinai who are involved in your care or treatment. The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example:

- The Mount Sinai Program for the Protection of Human Subjects is responsible for overseeing research on human participants and may need to see your information.
- If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- I*f the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.*

Who, outside Mount Sinai, might receive your PHI?
As part of the study, the Lead Researcher, research team and others in the Mount Sinai workforce may disclose your PHI, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Lead Researcher.)

- The United States Department of Health and Human Services (DHHS) and the Office of Human Research Protection (OHRP) (the government organization that is responsible for protecting human research participants).

In all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Lead Researcher will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board (IRB) allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, *OHRP, as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access.* The results of this research may be published. However, your name and other identifying information will be kept confidential.

For how long will Mount Sinai be able to use or disclose your PHI?
Your authorization for use of your PHI for this specific study does not expire.

Will you be able to access your records?
During your participation in this study, you will have access to your medical record and any study information that is part of that record. The research team is not required to release research information to you that is not part of your medical record.

Do you need to give the researchers permission to obtain, use or share your PHI?
NO! If you decide not to let the research team obtain, use or share your PHI, you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment, or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?
If you decide to stop being in the study, please contact the Lead Researcher or the research staff. The research team may ask you whether they can continue to collect information from your medical record. You will also have to decide if you wish to limit the continued use of the information collected during the study. Under US privacy laws you may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page.

Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected, but only to complete this research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If researchers are reviewing your medical records or asking questions about your medical history or conditions, it is possible that they may learn information related to your HIV status. If that is the case, the following information concerns you. If researchers are not reviewing your medical records or asking questions about your medical history or conditions, then you may ignore the following section.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 416-0197. These agencies are responsible for protecting your rights.

How the Institutional Review Board (IRB) can help you:

This research has been reviewed and approved by an Institutional Review Board (IRB). You may reach a representative of the Mount Sinai Program for Protection of Human Subjects at telephone number (212) 824-8200 during regular work hours (Monday-Friday, 9am-5pm, excluding holidays) for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

ADULT PARTICIPANT:

Your signature below documents your permission to take part in this research study and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

_____	_____	_____	_____
Signature of Participant	Printed Name of Participant	Date	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

_____	_____	_____	_____
Signature of Consent Delegate	Printed Name of Consent Delegate	Date	Time

WITNESS SECTION:

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

_____	_____	_____	_____
Signature of Witness	Printed Name of Witness	Date	Time