Use of Urinary Biomarkers to Quantify Degree of Renal Parenchymal and Urothelial Damage During Ureteroscopy
PI: Mantu Gupta
NCT05350423
Document Date: 1-10-2023

STUDY INFORMATION:

Study Title: Use of Urinary Biomarkers to Quantify Degree of Renal Parenchymal and Urothelial Damage During Ureteroscopy

Principal Investigator (Head Researcher): Mantu Gupta, MD

Physical Address: [redacted], New York, NY 10019

Mailing Address: [redacted], *New York, NY 10019*

Phone: 212-241-1272

SUMMARY OF THIS RESEARCH STUDY:

In medicine there are many unanswered questions. A research study is when scientists try to answer a question about something that we don't know enough about. Participation in a research study may or may not directly help you or others. Participation is entirely voluntary. It is completely up to you whether or not you take part. You can also change your mind at any time and it will not affect your ability to get medical care within the Mount Sinai Health System.

The purpose of this research study is to collect information regarding if there is any kidney damage after kidney stone surgery from urine samples.

If you choose to participate, there will be no additional visits required, 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 and are used interchangeably for kidney stone surgery for your regular care. For this research study, we will deliberately be using one laser over another to see if the type of laser used plays a role in kidney damage after surgery. You will undergo surgery as planned with Dr. Gupta, but you will provide a small urine sample before and after surgery, and at your stent removal appointment. The urine samples will be analyzed for kidney injury markers in our lab. There are no costs to participating in this study, and you will not be paid to participate in this study. We will store your urine samples for the duration of the study, which is expected to be completed within a year.

There is also a risk of loss of private information, but there are procedures in place to minimize this risk.

Participating in this research will not benefit you.

If you are interested in learning more about this study, please continue to read below.

PARTICIPATION IN THIS RESEARCH STUDY:

This research study will be fully explained to you by a member of the study team. Feel free to ask all the questions you want before you make a decision about whether or not to participate. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

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

Funds for conducting this research are provided by Mount Sinai.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

Your participation in this research study is expected to last 10 days.

The number of people expected to take part in this research study is 108. No participants will be enrolled outside the Mount Sinai Health System.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved.

During your initial consultation with Dr. Gupta, 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. 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.

.

While you are asleep under anesthesia, Dr. Gupta will empty your bladder and collect about a teaspoon of urine from your bladder at the beginning of the surgery. This is also part of your regular care, because a preoperative urine sample is always sent to the Mount Sinai lab at the beginning of the procedure. There is no risk to this procedure, and the only difference is that a portion of urine will be set aside for research.

About one hour after surgery, a member of the research team will collect urine from your catheter (a tube used to collect urine from the bladder), or they will ask you to provide a urine sample if you do not have a catheter placed during surgery.

After the procedure, 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. It should be noted that in order to complete the study patients must have a ureteral stent placed during surgery, so if you agreed to participate but did not require a stent you will be notified of your exclusion from the study following the procedure.

If a stent was placed, you will be asked to follow up in the clinical office approximately 10 days surgery to have the stent removed. You will be asked to provide a urine sample (about 2 teaspoons in volume).

Your study involvement is complete once the urine samples have been given.

USE OF YOUR DATA AND/OR SPECIMENS:

In the future, your identifiable information may be removed from the private information and/or samples that are collected as part of this research. After this removal, the information and/or samples could be used for future research studies or shared with other research teams for future research studies. You will not be informed of the details of specific research that is done with your medical information and biospecimens. That means that a research project might be done that you would not consent to if provided with the details of that research project.

This research will not include whole genome sequencing.

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 10 days and access your medical records.
- Provide a urine sample at your follow up appointment approximately 10 days after surgery.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will not be paid for participating in this research study. Being in this research study will not lead to extra costs to you.

Being in this research study will not lead to extra costs to you. The tests, procedures and exams that you will receive in this study are considered routine medical care ("standard of care") for your medical condition and would be recommended whether you take part in this study or not. Costs for routine care will be billed to you or your insurance company. If your insurance does not pay for your routine medical care you will be responsible for paying any deductible, co-insurance or co-payments for those services, and for any non-covered or out-of-network services.

POSSIBLE BENEFITS:

You are not expected to get any benefit from taking part in this research study. Others may not benefit either. However, we hope the information from this study will provide valuable data on the safety of kidney stone surgery.

REASONABLY FORESEEABLE 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 we will not give researchers your name, we will give them basic information such as your race, ethnic group, and sex. 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 even promote discrimination.
- Privacy Risks - Your name and other information that could directly identify you (such as address, date of birth or social security number) will never be placed into a scientific database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future. Since the database includes genetic information, a break in security may also pose a potential risk to blood relatives as well as yourself. For example, it could be used to make it harder for you (or a relative) to get or keep a job or insurance. If your private information was misused it is possible you would also experience other harms, such as stress, anxiety, stigmatization, or embarrassment from revealing information about your family relationships, ethnic heritage, or health conditions.

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you.

You can also have the ureteroscopy described in this study even if you decide not to be a part of the study.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you believe that you have suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you are otherwise entitled.

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

If you decide you don't want your samples and/or data to be used for research anymore, you can contact the researcher and ask to have your samples and/or data removed from future use. If any samples or data have already been shared without your identity, it won't be possible to retrieve them because no one will know who you are. Samples and data that have already been used will not be affected by your decision. Any samples and/or data that are still linked to your identity by a code the researcher has will be withdrawn so that no future sharing of your samples and/or data will take place. If your samples have already been deposited in an external repository, the study team will request that your samples be removed.

Withdrawal without your consent: The study doctor, the sponsor or the institution 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 study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If specimens or data have been stored as part of the research study, they too can be destroyed without your consent. More possible reasons for removal from the study include not needing a ureteral stent after surgery, missing your follow-up appointment, or noncompliance with the protocol.

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 Principal Investigator at phone number 212-241-1272.

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours 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 subject.
- You want to get information or provide input about this research.

DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/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 you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

What protected health information is collected and used in this study, and might also be shared with others?

As part of this research project, the research team at the hospital(s) involved in the research will collect your demographic and identifying information like your name, date of birth, address, telephone number, and your email address, related medical information like family medical history, and current and past medications or therapies, information from physical examinations, such as blood pressure reading, heart rate, height/weight and lab results.

Medical records will be obtained from the referring physician from the Department of Urology at the Icahn School of Medicine at Mount Sinai.

During the study the researchers will gather information by:

- taking a 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 and procedures explained in the description section of this consent.

Why is your protected health information being used?
Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

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 School's Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, 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 protected health information?
As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your protected health information, 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 Principal Investigator.)

- The United States Department of Health and Human Services and the Office of Human Research Protection.

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 Principal Investigator 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 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, *the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services 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. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

For how long will Mount Sinai be able to use or disclose your protected health information?
Your authorization for use of your protected health information 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 investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?
NO! If you decide not to let us obtain, use or share your health information 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?
You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your protected health information.

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, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

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) 306-5070. These agencies are responsible for protecting your rights.

ADULT PARTICIPANT:

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

Signature of subject	Printed Name of Subject	Date	Time [required if used for FDA documentation purposes]

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

Signature of consent delegate	Printed Name of consent delegate	Date	Time

WITNESS SECTION:

When a witness is required to observe the consent process, it should be documented below (for example, when subject is illiterate, visually impaired, or this document accompanies a short form consent).

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 subject, and that consent was freely given by the subject.

Signature of Witness	Printed Name of Witness	Date	Time