STUDY INFORMATION:

Study Title: International, prospective snapshot collaborative audit of acute diverticulitis (DAMASCUS)

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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 explore and compare the different types of treatment strategies used in subjects presenting with a condition called acute diverticulitis, which is an infection of the colon. The treatment for this condition depends on its common symptoms and can vary from medical management to surgical procedure like the removal of the diseased portion of the colon. In the past, a few studies have been conducted by reviewing the subject's medical charts and a few studies have reported their treatment strategy, but there is no worldwide consensus regarding the treatment of this condition (and decrease in the mortality rates).

This study is being done worldwide to determine whether different parts of the world use different treatment strategies. Subjects will be followed from the time the diagnosis is confirmed and the treatment starts. They will be observed up to 6 months to see if there is an association between initial treatment strategy and 30-day and 6-month outcomes.

Our goal is to collect data about previous history of management, presentation, 30-day clinical outcomes, and 6-month readmission/re-intervention rates. This will be achieved by extensive collection of information on patients undergoing conservative, radiological, and/or surgical treatment for this condition and the evaluation of events that will follow. Routine patient and clinical data will be recorded electronically in a secure web platform.

If you choose to participate, you will be asked to consent for the study after your diagnosis is confirmed. You will be observed for 6 months and the standard of care provided by your doctor will be collected via your medical charts. There are no research related visits and all your visits are of usual care. The duration of your participation is 6 months from your treatment initiation.

If you are admitted elsewhere (other than Mount Sinai Health System), we will contact you via phone to collect the missing health information (described in detail under section–Description of What's Involved).

The phone call might take half an hour (approximately) of your time depending on the missing information to be collected.

No extra cost is associated with your participation in the study and you will not be compensated for your participation in the study.

The main risk to you if you choose to participate is loss of private information; this risk always exists, but there are procedures in place to minimalize the 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 bowel condition called acute diverticulitis, for which you are receiving treatment.

Funds for conducting this research are provided by Mount Sinai Health System.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

Your participation in this research study is expected to last 6 months from the first visit for this condition (index admission).

The number of people expected to take part in this research study at sites within the Mount Sinai Health System is about 75. The total number of people expected to take part in this research study across all sites is approximately 4,000.

DESCRIPTION OF WHAT'S INVOLVED:

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

Index admission:

After you give consent to participate in this study, researchers will access and collect your past medical information. We will be collecting information about main disease state, its presentation and characteristics, previous surgeries and hospital visits, previous medication usage, and any risk factors for return of disease.

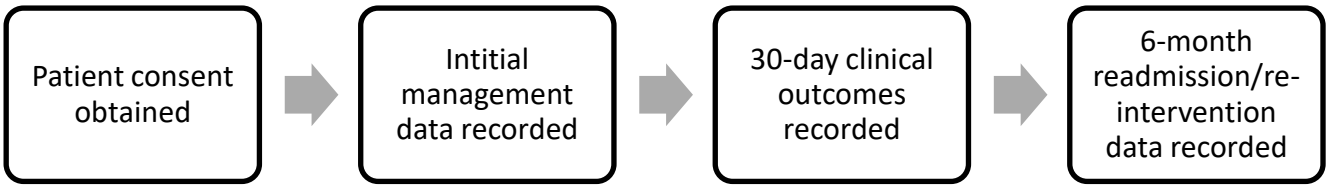
Your medical information will be accessed for information regarding treatment strategies used from index admission up till discharge. We will be collecting information about length of stay, any radiological procedures, treatment details, and/or surgical procedures. If you have any surgical procedure or any kind of intervention, we will be collecting information such as type of procedure, date of procedure, surgical findings etc. If more than one treatment regimen is used, then information about each regimen will be recorded.

First month after index admission:

We will record your 30 day progress post treatment. If applicable, information on any complications, readmission, any intervention, and any disease-specific information that affect treatment strategy will be documented. This follow up information will be collected from your medical records. If you are admitted elsewhere (other than Mount Sinai Health System), we will contact you via phone to collect all the above information.

Six months after index admission:

We will be collecting follow up information such as readmission and/or re-intervention. If applicable, any data regarding treatment strategies will be recorded. This follow up information will be collected from your medical records. If you are admitted elsewhere (other than Mount Sinai Health System), we will contact you via phone to collect all the above information.



The research activities will take place at Mount Sinai Hospital, Mount Sinai West, and Mount Sinai Queens. As part of research, we are only collecting data from your medical records. All the treatment and/or procedures you receive is standard of care. If you are admitted elsewhere (other than Mount Sinai Health System), we will contact you via phone to collect all the above information. All your visits and procedures are standard of care and are not research related. The research team and your treating physician will be carrying out the research activities.

USE OF YOUR DATA AND/OR SPECIMENS:

In the future, your identifiable information may be removed from the private information that are collected as part of this research. After this removal, the information 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. That means that a research project might be done that you would not consent to if provided with the details of that research project.

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: answering any follow-up questions researchers may have over the phone.

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. You will not be reimbursed for your travel or time that may be required for study visits.

POSSIBLE BENEFITS:

You are not expected to get any benefit from taking part in this research study. Others may not benefit either. However, possible benefits to others include that the information gained from this study may be beneficial to the research and medical community. The information we learn from this study may help us to better treat future subjects who need treatment for a similar condition like yours.

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.
- 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.

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. If you decide not to participate in this study, you will still receive medical care.

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.

You may also 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 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 events (bad effect) from participating in the research study.

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 data 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 Principal Investigator at phone number 212-241-3547 or 212-241-8250.

If you experience an emergency during your participation in this research, contact 911 or go to the emergency room.

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 name, address, telephone numbers, dates directly related to the individual (birth, admission, discharge, date of death, etc.), email address, and medical records number.

Portions of your previous and current medical records that are relevant to this study, including but not limited to diagnosis (es), history and physical, laboratory or tissue studies, radiology studies, and procedure results.

The researchers will also get information from your medical record at various sites within the Mount Sinai Health System.

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 Principal Investigator may also use and share the results of these tests and procedures to treat you in collaboration with others in the Mount Sinai Health System.

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. If 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.)

- Other collaborating research center(s) and their associated research/clinical staff who are working with the investigators on this project: Birmingham Surgical Trials Consortium Research data coordinating office and/or their representative(s) who will be responsible for collecting results and findings from all the centers: Birmingham Surgical Trials Consortium
- Contract Research Organization (whose job is to help organizations fulfill their responsibilities in the research and development process): Birmingham Surgical Trials Consortium
- 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