22-004680

A Phase II Study of Robotic Cytoreduction and Hyperthermic Intraperitoneal Chemotherapy (HIPEC) for Patients with Gastric Cancer and Limited Peritoneal Metastasis: ROBO-CHIP trial

NCT05753306

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MAYO CLINIC

Name and Clinic Number

Approval Date: July 9, 2025

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: A Phase II Study of Robotic Cytoreduction and Hyperthermic Intraperitoneal Chemotherapy (HIPEC) for Patients with Gastric Cancer and Limited Peritoneal Metastasis: ROBO-CHIP trial

IRB#: 22-004680

Principal Investigator: Travis Grotz, MD and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to see if a minimally invasive robotic approach to your planned procedure of stomach cancer removal and intraoperative chemotherapy in the abdomen can improve your recovery after surgery compared to the traditional open large incision approach. You have been asked to take part in this research because you were diagnosed with stomach cancer with limited low volume peritoneal metastasis and/or positive peritoneal cytology and you undergoing robotic cytoreduction and hyperthermic-intraperitoneal chemotherapy (HIPEC).
What's Involved	Study participation involves blood collection prior to your surgery. We will also collect peritoneal fluid and tissue at the time of surgery. You will need to be followed at Mayo Clinic after your surgery for 5 years.

	At each visit imaging and laboratory studies will be performed as is standard of care to assess for cancer recurrence. Additional blood will be collected for research at that time. .
Key Information	The purpose of this study is to assess your disease/condition and your outcomes after undergoing robotic cytoreduction and hyperthermic intraperitoneal chemotherapy.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep.. A copy of this form will be put in your medical record.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

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Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator:** Dr. Travis Grotz **Phone:** (507) 284-1529 **Study Team Contact:** Colorectal Surgery Clinical Research Unit **Phone:** (507) 422-9153 **Institution Name and Address:** Mayo Clinic 200 First St SW Rochester, MN 55905
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Participant Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Other Information:

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.

Why are you being asked to take part in this research study?

You have been asked to take part in this research because you were diagnosed with stomach cancer with limited low volume peritoneal metastasis and/or positive peritoneal cytology and you undergoing robotic cytoreduction and hyperthermic-intraperitoneal chemotherapy (HIPEC).

Why is this research study being done?

This study is being done to determine if the minimally invasive robotic approach to surgery results in fewer complications and quicker recovery compared to the traditional open large incision approach. We also want all aspects of your recovery as well as the effectivness of the procedure on treating your cancer..

Information you should know

Who is Funding the Study?
This study will be funded by the Mayo Clinic Department of Surgery, Intuitive, Inc. and benefactor funding.

Information Regarding Conflict of Interest:
Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

How long will you be in this research study?

Your participation in this research study will be for up to 5 years after your surgery. After that, your medical record will be reviewed once a year for life.

What will happen to you while you are in this research study?

If you agree to participate, prior to your surgery, you will be asked to complete a blood draw of 10 mL (approximately 2 teaspoons).

Within 4-6 weeks after your surgery, A second 10 mL blood draw sample will be collected.

Residual peritoneal fluid and tissue collected that is not needed for your standard of care will be collected at the time of your surgery.

Your biospecimen samples may be stored at Mayo Clinic past the duration of this research and will be used for future research.

Optional Research Blood Collection
You are also being asked to participation in optional research blood collection that would be obtained at regular scheduled clinical blood draws for cancer surveillance.

If you choose to participate an additional 10mL of blood may be collected at the time of a clinical blood draw. The optional blood draws would not be before you have completed your 4–6-week blood draw for the main study.

You do not have to be in the Optional Research Blood Collection to be in the main study. Please read the following statements and mark your choice:

I agree to participate in the optional blood test:

☐ Yes ☐ No Please initial here: _____Date: _____

What are the possible risks or discomforts from being in this research study?

The risks of drawing blood include pain, bruising, lightheadedness, and/or fainting, or rarely, infection at the site of the needle stick.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

There are minimal risks from a biospecimen standpoint.

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop, and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- If it is in your best interest,
- If you don't follow the study procedures,
- If the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

What if you are injured from your participation in this research study?

Where to get help:
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?
Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

What are the possible benefits from being in this research study?

We anticipate that the robotic procedure will result in improved recovery from this operation. However, this is not known for sure, hence the study.

It is possible that participation in this study may not make your health better. Information collected in this study may help people with gastric cancer in the future.

What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information. You may choose not to take part in this study. However, robotic cytoreduction and HIPEC is only being offered on trial. You may choose to have this operation performed in the standard open fashion off trial. Other alternatives include continuing systemic therapy.

What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- Blood Sample Collection and Testing
- Tissue Sample Testing

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

You won't be paid for taking part in this study.

Will your information or samples be used for future research?

Identifiable information such as your name, Mayo Clinic number, or date of birth may be removed from your information or samples collected in this study, allowing the information or samples to be used for future research or shared with other researchers without your additional informed consent.

How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

As with all research, there is a chance that confidentiality could be compromised. Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. Methods to safeguard confidentiality include use of a coded study number unique to you, a password protected database, and storing research materials in a locked cabinet.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.

- Other Mayo Clinic staff involved in your clinical care.
- Researchers involved in this study at other institutions
- The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you, but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
Plummer Building PL 3-02
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: researchparticipantadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts forever, unless you cancel it.

MAYO CLINIC

Name and Clinic Number

Approval Date: July 9, 2025

Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature