Utility of Intestinal Ultrasound as a Diagnostic Tool for the Evaluation of Pouchitis and Other Outcomes After Ileal Pouch-Anal Anastomosis: A Prospective Pilot Study

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MAYO CLINIC

Name and Clinic Number

Approval Date: **January 15, 2025**
Not to be used after: **January 14, 2026**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Utility of Intestinal Ultrasound as a Diagnostic Tool for the Evaluation of Pouchitis and Other Outcomes After Ileal Pouch-Anal Anastomosis: A Prospective Pilot Study

IRB#: 23-012169

Principal Investigator: Dr. Darrell S. Pardi 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 evaluate the performance of intestinal ultrasound in ulcerative colitis patients with a J-pouch. You have been asked to take part in this research because you have ulcerative colitis and had a prior pouch surgery.
What's Involved	Study participation involves a onetime visit with an intestinal ultrasound performed. You will be asked to complete a questionnaire about your experience during the ultrasound once it is completed. The study team will be reviewing your medical chart for additional information also.
Key Information	Your decision will not change the access to medical care you get at Mayo Clinic now or in the future if you choose not to participate or discontinue your participation.

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.

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. Darrell S. Pardi **Phone:** (507) 284-2407 **Study Team Contact:** Patricia P. Kammer **Phone:** (507) 538-1827 **Institution Name and Address:** Mayo Clinic 200 First Street 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

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

You are being asked to take part in this study because you have ulcerative colitis and underwent an ileal pouch-anal anastomosis surgery.

Our plan is to have about 109 people take part in this study at Mayo Clinic.

Why is this research study being done?

Ulcerative colitis is a chronic inflammatory bowel disease and carries a significant amount of disease burden. After an ileal pouch-anal anastomosis surgery patients can develop pouchitis (inflammation of the pouch). We are trying to determine if intestinal ultrasound can be used to evaluate this and other conditions.

How long will you be in this research study?

You will only have a one-time ultrasound appointment and visit.

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

A trained ultrasound technician will perform an ultrasound of your J-pouch and will collect images during the procedure. During this ultrasound you may experience mild discomfort as the ultrasound technician guides a transducer over your body. The ultrasound will include your abdomen, and perianal area. If you are female, it may include a special transducer that is inserted into your vagina. Afterwards you will complete a survey either in person or by mail or electronically with questions about your experience. Your contact information will be collected if you do not wish to complete it in person for the purposes of sending you the survey. There will be no further visits afterwards.

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

Other than undergoing an ultrasound procedure, you will not experience any additional risk by taking part in this study. General: ultrasound is usually painless. However, you may experience mild discomfort as the sonographer guides the transducer over your body, especially if you're required to have a full bladder, or inserts it into your body. The ultrasound will include your perianal. If you are female it may include a special transducer that is inserted into the vagina. Some subjects may find the transducer placement into their vagina to be personally uncomfortable. Wherever possible, the ultrasound appointment will be grouped with your routine clinic appointments to minimize the number of trips to Mayo Clinic.

Your clinical doctor will discuss the treatments related to your inflammatory bowel disease and this will not be in any way determined by this research study.

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

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. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

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

There is no direct benefit to you for taking part in this study. Others with ulcerative colitis may benefit in the future from what we learn in this research study.

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.

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

You will not need to pay for tests and procedures which are done just for this research study.

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These tests and procedures are:

- One-time intestinal ultrasound

If some of these tests are performed by your health care team as part of your clinical care, we will not repeat them. However, you and/or your insurance will need to pay for these and all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

If the results of tests or procedures performed for research may be useful for your health care, you may be notified. If you decide to follow up, any further medical testing will be considered part of your clinical care and will not be paid for by the research study. Costs will be billed to you or your insurance.

If you have questions about any costs to you that may result from taking part in the research, please speak with the Principal Investigator. If you wish, arrangements can be made for you to speak with someone in Patient Financial Services about these costs.

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 will not be paid to participate in this research study. You will receive the option of, a one-day parking pass to help cover the cost of parking the day of your visit, or a meal card to the Mayo Clinic patient cafeteria, both of equal value.

Will your information or samples be used for future research?

Any information collected as part of this research project, even if identifiers are removed, will not be used or distributed for future research studies.

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.

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.
- Other healthcare providers involved in your clinical care.
- 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.

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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.

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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
200 1st Street SW
Plummer Building PL 3-02
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 until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

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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