18-010128

# Randomized Control Trial Comparing Somatostatin Analogues with Perioperative Antibiotics versus Prolonged Antibiotics

NCT04329039

Document Date: 12/05/2024

MAYO CLINIC

Name and Clinic Number

**Approval Date:** **December 5, 2024**
**Not to be used after:** **December 4, 2025**

# RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

**Study Title:** Randomized control trial comparing somatostatin analogues with perioperative antibiotics versus prolonged antibiotics

**IRB#:** 18-010128

**Principal Investigator:** Dr. Michael Kendrick 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 compare 2 different courses of antibiotic treatment combined with a somatostatin analogue (Octreotide) to determine how length of antibiotic treatment after pancreatic surgery affects the duration of Hospital stay as well as the incidence of pancreatic fistula.<br><br>You have been asked to take to take part in this research because you have a pancreatic condition that will be treated with what is called a Whipple procedure. You will also be treated with octreotide and antibiotics.<br><br>Octreotide is a subcutaneous (just under the skin) injection that is administered in the hospital. These injections will need to be administered every 8 hours for 7 days. This antibiotic treatment with octreotide is a clinical standard of care, meaning you would have this treatment even if you were not taking part in this study. |

MAYO CLINIC

Name and Clinic Number

**Approval Date:** **December 5, 2024**
**Not to be used after:** **December 4, 2025**

| | |
|---|---|
| **What's Involved** | If you agree to take part in this study, you will be assigned by chance (like a coin toss) to 1 of 2 groups of therapy with octreotide and different durations of antibiotic treatment. The dosing will still be the same amount for either group.<br><br>Your study team will monitor your clinical records and collect data to learn about how and if you develop a pancreatic fistula, and how well it is treated with the antibiotics you are taking. |
| **Key Information** | You do not have to take part in this study. You will receive the same type of care for pancreatic fistula even if you do not take part in this study. The risks associated with study participation are completely described later in this form, be sure to review them carefully. While our study is research and not guaranteed to offer help, you may benefit from the treatment if it works. |
| **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 providers 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.

MAYO CLINIC

Name and Clinic Number

**Approval Date:** **December 5, 2024**
**Not to be used after:** **December 4, 2025**

## Contact Information

| If you have questions about … | You can contact … |
|---|---|
| ▪ Study tests and procedures<br>▪ Materials you receive<br>▪ Research-related appointments<br>▪ Research-related concern or complaint<br>▪ Research-related injuries or emergencies<br>▪ Withdrawing from the research study | **Principal Investigator:** Michael Kendrick, M.D.<br>**Phone:** [redacted]<br><br>**Study Team Contact:** [redacted]<br>**Phone:** [redacted]<br><br>**Institution Name and Address:**<br>Mayo Clinic<br>200 1st St SW<br>Rochester, MN 55905 |
| ▪ Rights of a research participant | **Mayo Clinic Institutional Review Board (IRB)**<br>**Phone:** [redacted]<br>**Toll-Free:** [redacted] |
| ▪ Rights of a research participant<br>▪ Any research-related concern or complaint<br>▪ Use of your Protected Health Information<br>▪ Stopping your authorization to use your Protected Health Information<br>▪ Withdrawing from the research study | **Research Participant Advocate (RPA)**<br>**(The RPA is independent of the Study Team)**<br>**Phone:** (507) 266-9372<br>**Toll-Free:** (866) 273-4681<br><br>**E-mail:** ResearchParticipantAdvocate@mayo.edu |
| ▪ Billing or insurance related to this research study | **Patient Account Services**<br>**Toll-Free:** (844) 217-9591 |

**Other Information:**
A description of this clinical trial will be available on https://www.mayo.edu/research/clinical-trials/. This Web site will not include information that can identify you. You may search this Web site at any time.

MAYO CLINIC

Name and Clinic Number

**Approval Date:** **December 5, 2024**
**Not to be used after:** **December 4, 2025**

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

You are being asked to take part in a study because you have a pancreatic condition that is going to be treated with a Whipple procedure and octreotide with antibiotics, and you may be at risk for a pancreatic fistula (leakage from the pancreas due to damaged pancreatic ducts).

The plan is to enroll about 400 people in this study at Mayo Clinic.

## Why is this research study being done?

A pancreatic fistula is a significant event that can happen after pancreatic surgery. It can cause severe complications after surgery and cause an increase in length of hospital stay. The standard treatment for a pancreatic fistula is a medication called octreotide plus antibiotics. In this study, 2 different durations of antibiotics plus octreotide will be compared to find out how the length of antibiotic treatment in addition to octreotide after pancreatic surgery affects the amount of time patients are hospitalized as well as how many patients develop pancreatic fistulas.

## Information you should know

**Who is Funding the Study?**
This study is being funded by Mayo Clinic.

## How long will you be in this research study?

You will be in the study for 90 days after your scheduled pancreatic surgery. Your study team will monitor your clinical records and collect data over those 90 days.

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

If you agree to be in this study, you will first sign this consent form before any study-related procedures are done. After surgery, if you are eligible for the study, we will assign you by chance (like a coin toss) to one of two groups. There will be 200 people in each group.

Both groups have the same standard of therapy for Octreotide but the antibiotic treatment groups will have different durations. The Octreotide is administered under the skin (subcutaneous) and antibiotic treatment is administered through IV. The dosing will still be the same amount for either group. Group 1 and Group 2 treatments are still considered clinical standard of care, meaning you would have this treatment even if you were not taking part in this study.

**Group 1:** Standard therapy with octreotide (150mcg subcutaneous every 8 hours for 7 days) PLUS 24 HOURS of antibiotics after surgery. (Group 1 is Global Standard of Care)

**Group 2:** Standard therapy with octreotide (150mcg subcutaneous every 8 hours for 7 days) PLUS 5 DAYS of antibiotics after surgery.
(Group 2 is Mayo Clinic Standard of Care)

Neither you nor the Principal Investigator can choose your study group, but you will know which study group you have been assigned to because of the length of time you take antibiotics.

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

Your doctor will discuss the details and risks of octreotide and antibiotic treatment, as these are part of your standard clinical care.

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. 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?

This study may or may not make your health better. However, this information may help others in the future who develop pancreatic fistulas after pancreatic surgery.

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

You don't have to be in this study to receive treatment for your condition. Your other choices include the standard of care treatment or other treatments that you may discuss with your doctor. Talk to the Principal Investigator or your doctor if you have any questions about any of these treatments or procedures.

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

You and/or your insurance will need to pay for all tests and procedures that are part of this research study because the procedures and tests involved are all standard of care, meaning you would basically receive the same treatment even if you did not participate in this study. Before you take part in this study, you should call your insurer to find out if the cost of these tests and/or procedures will be covered. You will have to pay for any costs not covered by your insurance.

**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 to take part in this research study.

MAYO CLINIC

Name and Clinic Number

**Approval Date:** **December 5, 2024**
**Not to be used after:** **December 4, 2025**

## Will your information or samples be used for future research?

Your information collected for this study will not be used or shared for future research studies even if the identifiable information such as your name, Mayo Clinic number or date of birth is removed.

## 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. Your data will be given a code, rather than your name or clinic number. All databases will be password protected, and all printed data will be kept in a locked file cabinet. All electronic data will be kept in a secured database/server accessible only by study personnel as authorized by the investigator.

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.
- 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.
- A group that oversees the data (study information) and safety of this 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, 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.

**Approval Date:** **December 5, 2024**
**Not to be used after:** **December 4, 2025**

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 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.

MAYO CLINIC

Name and Clinic Number

**Approval Date:** **December 5, 2024**
**Not to be used after:** **December 4, 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