IRB NUMBER: STUDY20230096
IRB APPROVAL DATE: 3/12/2024
IRB EFFECTIVE DATE: 3/12/2024
IRB EXPIRATION DATE: 1/18/2025

Project Title: CASE 2223: eXtended antibiotic prophylaxis for intermediate- and high-risk glands after pancreatoduodenectomy to reduce clinically relevant PostOperative Pancreatic Fistula: A phase 2 randomized control trial (X-POPF)

Sponsor: University Hospitals Cleveland Medical Center

Principal Investigator: Lee M. Ocuin, MD, FACS

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are being invited to take part in this research study because you are being scheduled for a pancreatoduodenectomy (your surgeon may also call it a Whipple procedure) at University Hospitals Cleveland Medical Center. This research study is evaluating whether an antibiotic given after surgery can prevent complications from the pancreatoduodenectomy.

Things I should know about a research study

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Introduction/Purpose

Your surgeon has indicated that you are planned to undergo a pancreatoduodenectomy, also known as Whipple procedure. This procedure is sometimes complicated by leaking of pancreatic fluid, known as a postoperative pancreatic fistula. This condition results from a leak at the place that the pancreas is connected to the bowel. This leakage can make patients sick and lead to other complications, like sepsis and bleeding. This leakage may also require another surgery or procedure to correct or control.

To help prevent this complication we are conducting a clinical trial to test if extended antibiotic prophylaxis is effective in preventing development of pancreatic fistula. If you agree to take part in this study, your risk of developing a postoperative pancreatic fistula is calculated in the operating room. If this risk is high enough you will be randomized to either standard antibiotics (less than 24 hours) or 10 days of antibiotics following surgery. All parts of your postoperative care will be done according to the study protocol regardless of which group you have been randomized to. The antibiotics will be delivered through your vein while you are in the hospital, and by mouth after discharge. All care, including lab tests, imaging, and hospital say, will be

performed regardless of if you are part of the clinical trial or not. We will be enrolling 96 patients at UH to participate in the study.

Key Study Procedures
If you agree to participate in this study, you will be randomized at the time of your surgery, and depending upon the risk of developing a leak of pancreatic fluid, to standard of care or prophylactic antibiotics. Participants are twice as likely to be assigned to the antibiotic (treatment) arm of the study. The study lasts 90 days from your day of surgery. More detailed information about the study procedures can be found under "Detailed Study Procedures."

Key Risks
The biggest risk is an adverse reaction to the antibiotics. The antibiotics administered in this study are penicillin-class drugs. You should not participate in this trial if you have had any reaction to these drugs or drug types in the past. Other risks of the antibiotics include infectious diarrhea or the development of antibiotic resistant bacteria. More detailed information about the risks of this study can be found under "Detailed Risks."

Benefits
If you are assigned to the extended antibiotic arm, your risk of having a postoperative pancreatic fistula may be lower, however, there is no proven benefit to the treatment, and patients assigned to the standard arm may have similar or better outcomes than those assigned to the treatment arm. You are also helping the care of patients who undergo this surgery in the future.

Alternatives to Study Participation
Participation in this study is voluntary. There are no consequences for you if you do not participate. If you chose not to participate in this trial it will be up to your surgeon if he believes that you should receive antibiotics in a similar manner following surgery, and they will discuss their plan with you.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Detailed Study Procedures
Your participation in this study will include randomization to either of the following regimens:

- Extended antibiotics for a total of 10 days. After surgery piperacillin/tazobactam will be given IV every 6 hours. If you are discharged before 10 days, you will be given amoxicillin/clavulanic acid to take by mouth to complete 10 days total.

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- Standard of care antibiotics - piperacillin/tazobactam given IV just before surgery and for no more than 24 hours after.
- Randomization is 2:1 which means you are twice as likely to be in the extended antibiotic group than the standard of care antibiotic group.
- All of the standard postoperative care for patients undergoing pancreatoduodenectomy (Whipple procedure) is part of the study protocol, including drains placed during surgery, the tests for pancreatic fluid leaking from those drains, drain removal, and deciding when to perform repeat imaging tests. Any choices in your care are at the discretion of your surgeon.
- Otherwise your care will be identical patients who have had the same surgery, and all appointments, lab tests, and imaging studies will be done as part of standard postoperative care. This clinical data will be collected as part of the trial.

Detailed Risks

There is also a risk that you could have side effects from the study drug(s)/study approach.

Here are important points about side effects:

1. The study doctors do not know who will or will not have side effects.
2. Some side effects may go away soon, some may last a long time, or some may never go away.
3. Some side effects may interfere with your ability to have children.
4. Some side effects may be serious and may even result in death.

Here are important points about how you and the study doctor can make side effects less of a problem:

1. Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
2. The study doctor may be able to treat some side effects.
3. The study doctor may adjust the study drugs to try to reduce side effects.

Risks related to piperacillin/tazobactam:

The most common adverse events associated with piperacillin/tazobactam are listed below with the percentages given in piperacillin/tazobactam single therapy trials:

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Common (more than 1 in 10)	Uncommon (less than 10 in 100)	Rare (less than 1 in 100)
Diarrhea (11.3%)	Constipation (7.7%) Nausea (6.9%) Vomiting (3.3%) Heartburn (3.3%) Abdominal pain (1.3%) Fever (2.4%) Candidiasis/yeast infection (1.6%) Headache (7.7%) Insomnia/trouble sleeping (6.6%) Rash (4.2%) Pruritus/itching (3.1%) Phlebitis/vein inflammation (1.3%)	Injection site reaction (≤1%) Rigors/chills (≤1%) Anaphylaxis/allergic reaction (≤1%) Colon inflammation/infection (pseudomembranous colitis; ≤1%) Low blood sugar (≤1%) Myalgia/muscle aches (≤1%) Arthralgia/joint aches (≤1%) Purpura/purple spots (≤1%) Thrombophlebitis/vein clot and inflammation (≤1%) Hypotension/low blood pressure (≤1%) Flushing (≤1%) Epistaxis/nose bleed (≤1%)

The most clinically relevant adverse events are the development of infectious diarrhea, *C. Difficile.* This is a colon infection caused by exposure to antibiotics. There is also the development of kidney disfunction, which may require a reduced dose or stopping the medication.

It is important to note that Piperacillin/Tazobactam is also given before and during surgery, even if you are not participating in the clinical trial.

Risks related to amoxicillin/clavulanic acid:

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The most common adverse events associated with Amoxicillin/Clavulanic Acid use are listed below:

Common (more than 1 in 10)	Uncommon (less than 10 in 100)	Rare (less than 1 in 100)
	Diarrhea/Loose Stools (9%) Nausea (3%) Vomiting (1%) Skin rashes and Urticaria (3%) Vaginitis (1%)	

The most concerning adverse events for this medication are also the colon infection, *C. Difficile* colitis.

4. Anaphylactic Reaction. Even in the absence of prior allergies or intolerances, patients may develop an anaphylactic reaction to one of more of the study drugs. In this case the medication would be halted and supportive care given.
5. The risk of breach of confidentiality
    a. There is a risk of breach of confidentiality which means that someone who is not listed in this form might view your data either by accident or from malicious actions they take to hack the data. We are protecting against this by (1) removing information typically used to identify the subject (e.g., name, address, date of birth) from information stored in the study database and assigning a code to the information; (2) securing, in a separate location, and limiting access to the key to link the subject's identity with the code assigned to their information; (3) limiting access to information stored in the study database as described in the consent form, including to the research team and affiliated Institutional Review Board and government authorities.
6. Risk of increased antibiotic resistance. Antibiotic use can lead to the development of bacteria that do not respond to those antibiotics used. This can make an infection more difficult to treat.
7. If new risks are discovered during the course of this research study, those risks will be communicated to *you*.

Consequences of Withdrawing or Being Discontinued from the Research

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The data collected on you to the point of withdrawal will remain part of the study database and may not be removed. The study team will ask if we can continue to collect standard of care data from your medical record.

Financial Information

- There are no additional costs to the subjects participating in this study. All aspects of pre-, intra-, and post-operative care are standard practice.
- If a subject chooses to withdraw from the study, there will be no costs to the subject.
- There will be no compensation for participation in this clinical trial.
- Co-pays may be incurred by subjects.

- **Notice for Managed Care (Medicare Advantage Plan) Beneficiaries**
  - Certain services provided to you as a participant in a clinical trial are allowable to be billed to, and paid by, your medical insurance. These services are referred to as "covered" clinical trial services. If you have a Medicare Advantage Plan as part of your medical insurance, the Centers for Medicare & Medicaid Services (CMS) require that traditional Medicare will be billed for those covered clinical trial services. When this occurs, you will remain responsible for paying the coinsurance and deductibles according your Medicare Advantage Plan. Your Medicare Advantage Plan should cover any associated cost share related to Medicare. Please speak with a financial counselor to understand what the specific financial impact will be for you associated with participating in this clinical trial.

Disclosure(s)

- If your doctor is also the person responsible for this research study, please note that he/she/they is interested in both your clinical care and the conduct of this research study. This disclosure is made so that you can decide if you want a second opinion regarding your participation in the study.

Research-Related Injury

In the event you suffer a research related injury as a result of being in this study, University Hospitals is available to provide medical treatment for such injury. Provision of such medical treatment does not imply any negligence or other wrongdoing on the part of University Hospitals or any of the physicians or other study personnel. If you believe that you have been injured as a result of participating in the study, please immediately contact the Principal Investigator or your study doctor at University Hospitals. If you cannot reach the Principal Investigator or your study

doctor, do not delay treatment. You may seek treatment by another doctor. If you are seen or treated by a doctor other than the Principal Investigator or your study doctor, you should inform such doctor that you are in this study and, if possible, take this document with you to assist with your treatment. Always contact the Principal Investigator or your study doctor to alert them of any treatment you receive for an injury or illness you experience during this Study.

The costs for medical treatment as a result of a research related injury may be billed to you or your medical insurance plan, if applicable. Medical insurance plans may or may not cover costs for medical treatment of research related injuries. If you have insurance, you should check with your medical insurance plan before deciding to participate in this research study. In the event your medical insurance plan covers some or all of the treatment costs, you may still be responsible for co-pays or deductibles as required by your medical insurance plan.

University Hospitals has not set aside any money to pay you or to pay for your treatment if you suffer a research related injury as a result of being in the study. There are no plans for University Hospitals to provide other forms of compensation (such as lost wages or other indirect losses) to you for research related injuries. You are not waiving any legal rights by signing this form, including the right to seek compensation for an injury. To help avoid injury, it is very important to follow all study directions.

Clinical Trial Information – ACTs or NIH-funded clinical trials

A description of this clinical trial will be available on http:///www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time to find out information about the trial and basic results.

Student/Employee Rights

Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor will the results be shared with your supervisor.

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Confidentiality

Data will be stored in the OnCore™ database and consent forms will be stored in a secure, doubly locked location. Identifiers will not be removed from your identifiable private information given that the outcomes of the study, mainly complications and pancreatic leak, must be managed in real time by your treating physician and team. No samples will be collected and stored, therefore there is no risk that samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data. The study statistician will have access to deidentified data for analysis upon conclusion of the study.

This study is collecting data from you. We would like to make these available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study, but it could also be unrelated. These studies may be done by researchers at this institution, other institutions, including commercial entities. Our goal is to make more research possible.

Your deidentified information may be shared with other researchers or databases. If your identifying information is removed from the data you provided, they may be shared without your additional consent. We cannot guarantee anonymity of your personal data even if identifying information is removed.

In addition, with your consent, we would like to share your identifiable or coded data with other researchers for future research. Coded data means personal identifiers are removed but a link to

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your identity exists. We will protect the confidentiality of your information to the extent possible. Coded information may also be submitted to federal or other databases/repositories.

It is your choice whether or not to let researchers share your coded data for research in the future. If you change your mind and no longer wish to have us store or share your identifiable/coded data, you should contact the study coordinator, Nikola Anusic ([redacted]) or Principle Investigator, Lee Ocuin ([redacted]). We will do our best to honor your request and retrieve any data that have been shared with other researchers or databases. However, there may be times we cannot. For example, if the data has already been used for new research.

Do you agree to allow for the sharing of your identifiable/coded data?

_____ YES, use my identifiable/coded data in other research studies

_____ NO, do NOT use my identifiable/coded data in other research studies

Can I stop taking part in this study?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

The study doctor will tell you about new information-n or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study requirements
- If the study is stopped by the sponsor, Institutional Review Board (IRB) or FDA.

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Privacy of Protected Health Information (HIPAA)

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled "Extended antibiotic prophylaxis for intermediate- and high-risk glands after pancreatoduodenectomy: A phase 2 randomized control trial" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Lee M. Ocuin, MD and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you: name, medical record number, address, details about your medical history, inpatient treatment, lab values, imaging results, and postoperative complications. This PHI will be used to determine if the receipt of prophylactic antibiotics reduced the rate of clinically significant postoperative pancreatic fistula, as well as other postoperative complications. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research:

- Case Comprehensive Cancer Center members and collaborators
- The Food and Drug Administration
- The Department of Health and Human Services
- The National Cancer Institute (NCI)
- Other Institutional Review Boards
- Data Safety and Monitoring Boards
- Other staff from the Principal Investigator's medical practice group that are involved in the research

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University Hospitals, including the Center for Clinical Research and the Law Department; any UH or CWRU employee required to process information for research, finance, compliance, or hospital operation, and Government representatives or Federal agencies, when required by law.

It is possible, that in the future, additional research sites may be added. In this event, your PHI that was collected during this research project may be shared with research personnel at these additional sites.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to:

Lee M. Ocuin, MD
Division of Surgical Oncology
University Hospitals Cleveland Medical Center
Seidman Cancer Center
11100 Euclid Avenue
Cleveland, OH 44106

If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

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Summary of Your Rights as a Participant in a Research Study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. De-identified data from this study may be published, presented, or otherwise made publically available. If this happens, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of Your Study Records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact Information

_____ has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Lee M. Ocuin, MD can also be contacted at [redacted] or [redacted]. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at [redacted] or write to: The Associate Chief Scientific Officer, Clinical Research Center, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside [redacted], Cleveland, Ohio, 44106-7061.

Signature

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Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

If enrolling adults, use the following signature block (complete all fields):

X		
Signature of Participant	Date	Time
X		
Printed Name of Participant		

If a witness is involved in the consent process (e.g., inclusion of illiterate individuals, non-English speaking individuals, or individuals who cannot physically sign), add the following signature block and attestation (complete all fields):

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

X		
Signature of Witness to Consent Process	Date	Time
X		
Printed Name of Person Witnessing Consent Process		

All studies must include the following signature block (complete all fields):

X		
Signature of person obtaining informed consent	Date	Time

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X
Printed name of person obtaining informed consent