21-004234

“Answers in Hours” A Randomized Controlled Trial Using Microbiome Metagenomics for Bile Duct Cultures

NCT05523154

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MAYO CLINIC

Name and Clinic Number

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Not to be used after: **October 20, 2023**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: "Answers in Hours" A Randomized Controlled Trial Using Microbiome Metagenomics for Bile Duct Cultures

IRB#: 21-004234

Principal Investigator: Nicholas Chia, PhD 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 study is to test an investigational device, called the Oxford Nanopore (ONT) GridION sequencing instrument, and a laboratory technique using ONT sequencing. The purpose of this study is to determine if ONT sequencing performed using the ONT GridION sequencing instrument will result in earlier detection and treatment of bacterobilia, which is bacteria in the bile (fluid created by your liver) that may lead to a post-surgery site infection. You have been asked to take part in this research because your provider has scheduled either a pancreaticoduodenectomy (also known as a Whipple procedure) or a total pancreatectomy (surgical removal of your pancreas) as part of your clinical care.
What's Involved	Study participation involves randomization to either standard laboratory testing alone vs standard laboratory testing along with ONT

	sequencing performed on bile collected at the time of surgery. The study team will review information from your medical record for 90 days after surgery to follow your clinical progress.
Key Information	Assignment to a study group will be random, like a flip of a coin. You will have a 50% chance of being assigned to either group. Your clinical care team will be aware of the group you are assigned to. There are no additional costs to participate. If you decide not to take part in this study, you will still receive your normal standard of care testing during your surgery.
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(s):** Nicholas Chia, Ph. D **Phone:** (507) 538-0614 **Study Team Contact:** CRS/HPB Research Team: **Phone:** (507) 422-4124 **Institution Name and Address:** 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

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.

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

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

You are being asked to take part in this study because your provider has scheduled either a pancreaticoduodenectomy (also known as a Whipple procedure) or a total pancreatectomy (surgical removal of your pancreas) as part of your clinical care.

The plan is to have about 140 people take part in this study at Mayo Clinic

Why is this research study being done?

The purpose of this study is to test an investigational device, called the Oxford Nanopore (ONT) GridION sequencing instrument, and a laboratory technique using ONT sequencing. The purpose of this study is to determine if ONT sequencing performed using the ONT GridION sequencing instrument will result in earlier detection and treatment of bacteriobilia (bacteria in the bile) that may lead to surgical site infections.

This study will be comparing the ONT sequencing results to the clinically used and routine laboratory tests done during surgery as the current standard of care, which entails bacterial and fungal culturing of bile.

This standard of care testing is performed by testing a sample of your bile (a fluid created by your liver) collected at the time of surgery.

Depending on how you are randomized, you will have either the ONT sequencing and standard of care testing or only standard of care testing of your bile (a fluid created by your liver) collected at the time of surgery. Your care team will be aware of the group you will be randomized to.

Information you should know

Who is Funding the Study?
Mayo Clinic is funding the study and covering costs related to running the study.

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?

You will be in the study until the research team has finished collecting information from your medical record which will be up to 90 days after your pancreas surgery.

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

If you agree to be in the study and provide consent, you will be asked to participate in the following:

Enrollment Visit
Before your scheduled pancreas surgery, you will meet with a member of the study team. During this visit, there will be a discussion of all study-related activities and a chance to ask any questions.If you agree to be in this study, you will first sign this consent form before any study-related procedures are done. The study team will then collect baseline demographic information for data collection such as age, sex, indication for surgery, ASA, major comorbidities, pre-operative biliary stenting/manipulation, and pre-surgical cholangitis, etc.

Surgery Visit
Sample Collection – Both Groups
During your surgery we will collect a small sample of bile to complete the laboratory testing for both group assignments.

Randomization
Once the sample of bile has been collected at the time of surgery, you will be randomized (like flipping a coin) to be assigned to either:

- **Group 1:** Standard of care laboratory testing only (the medical treatment you would be receiving if not participating in the study)

- **Group 2:** Standard of care laboratory testing + ONT sequencing which will be done for research
    - If you are randomized to Group 2 (standard of care laboratory testing + ONT sequencing), your clinical care team will use recommendations from ONT sequencing results to guide your antibiotics postoperatively. Your clinical care team will have access to standard of care laboratory testing to guide your antibiotics in the event the care team decides it is in your best interest to choose antibiotics based off of standard of care laboratory testing instead of ONT sequencing. This will be discussed with your clinical team and decisions will be made with the assistance of Surgical Clinical pharmacists.

Your clinical care team will be notified of your group assignment post-procedure.

Follow-up Data Collection

Record review

Information from your medical record will be collected for 90 days after your pancreas surgery to document your clinical progress.

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

The study may include risks related to standard of care antibiotic changes after surgery. Your doctor will discuss the risks associated with the antibiotics with you. There will be no alteration in the standard clinical postoperative care of patients in this study.

Risks associated with a false negative ONT sequencing result:

- If you are assigned to the ONT sequencing group, there is a small possibility you could have a false negative ONT sequencing result. You will always have the standard of care culture along with the ONT sequencing. Your clinical team will determine antibiotic treatment when the standard of care culture result is confirmed as positive

Confidentiality

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?

This study may not make your health better.

Others undergoing pancreas surgery 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. These tests and procedures are:

- Oxford Nanopore (ONT) Sequencing

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 will not be paid for taking part in this study.

There is a very small chance that some commercial value may result from the use of your sample and information. This could include new products like a test to diagnose a disease. If that happens, you will not be offered a share in any profits.

Will your information or samples be used for future research?

Your information or samples 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.

The study team will assign a code number to the study data. Only the study team will have access to the link between your identifying information and your study code number. Data stored on a computer will be password-protected and secure. Every effort will be made to keep medical information confidential. If the results of the research are made public, information that identifies you will not be used.

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.

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.

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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
201 Building 4-60
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.

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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