16-001243

Phase II Study of EUS-guided Verteporfin PDT in Solid Pancreatic Tumors (VERTPAC-02)

NCT03033225

Document Date: 05/05/2023

MAYO CLINIC

Name and Clinic Number

Approval Date: **May 5, 2023**
Not to be used after: **October 18, 2023**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Phase II study of EUS-guided verteporfin PDT in solid pancreatic tumors (VERTPAC-02)

IRB#: 16-001243

Principal Investigator: Dr. Vinay Chandrasekhara, MD and Colleagues

Please read this information carefully. It tells you important things about this research study. A member of our research team will talk to you about taking part in this research study. If you have questions at any time, please ask us.

Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision won't cause any penalties or loss of benefits to which you're otherwise entitled.
- Your decision won't 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.

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.

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 a copy of this form to keep. A copy of this form will be put in your medical record.

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CONTACT INFORMATION

You can contact …	At …	If you have questions about …
Principal Investigators: **Rochester** Dr. Vinay Chandrasekhara, MD **Study Team Contact:** **Rochester:** Kevin Buller **Florida** Herbert Wolfsen MD **Florida** Betsy Cayer CCRP	**Phone:** (507) 284-2687 **Phone:** (507) 255-5476 **Address:** Mayo Clinic Rochester 200 First St SW Rochester MN 55905 **Phone:** (904) 953-6319 **Phone:** (904) 953-7778 **Address:** Mayo Clinic Florida 4500 San Pablo Road, Jacksonville, FL 32224	▪ Study tests and procedures ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints ▪ Withdrawing from the research study ▪ Materials you receive ▪ Research-related appointments
Mayo Clinic Institutional Review Board (IRB)	**Phone:**(507) 266-4000 **Toll-Free:**(866) 273-4681	▪ Rights of a research participant
Research Participant Advocate (RPA) **(The RPA is independent of the Study Team)**	**Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipiantadvocate@mayo.edu	▪ Rights of a research participant ▪ Any research-related concerns or complaints ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information
Patient Account Services	**Toll Free:** (844) 217-9591	▪ Billing or insurance related to this research study

Other Information:
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.

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 been identified as someone who has locally advanced or small volume metastatic pancreatic cancers or other solid tumors that is unable to undergo surgical resection. The overall study plans to enroll 30 subjects. Mayo Clinic plans to enroll 15 subjects.

Why is this research study being done?

The goal of this project is to transform the management of pancreatic cancer in the locally advanced and metastatic phases. This will be done by using photodynamic therapy, a new type of laser device, in combination with systemic therapy.
We are doing research on this new method of treatment to find out if it is a less invasive option and is as effective as current treatment methods.

Information you should know

Who is Funding the Study?
This study is being funded by the National Institute of Health (NIH). The Principal Investigator or the institution will otherwise cover the costs related to running the study.

How long will you be in this research study?

You will be in the study for one year, or until you decide to discontinue treatment.

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

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

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	Patient Visit Schedule							
	Screening	Procedure Visit	Day 2	Day 3	Day 14	Month 3	Month 6	Month 12
Physical Exam	X		X	X	X	X	X	X
CT Scan	X			X		X	X	X
Bloodwork	X		X	X	X	X	X	X
Questionnaires	X				X			
Endoscopy		X						
Verteporfin Infusion and Photodynamic Therapy (PDT)		X						

Screening Visit

- During the screening visit, you will undergo a physical examination, you will have bloodwork and a CT scan done, and you will be asked to fill out quality of life questionnaires.

Procedure Visit

- An hour prior to the procedure, you will receive the study drug through an IV infusion. You will also be given an antibiotic to reduce the risk of inflammation before the procedure. The physician will direct the endoscope that has an ultrasound to your pancreas, and the treatment laser will be guided to the sites on your pancreas where the tumors are located. This will be done using an ultrasound to find the tumor and place a needle from inside the stomach or small intestine into the tumor. This is a standard procedure for obtaining tissue from a tumor. In this study, a special fiberoptic probe will be placed through the needle to allow light to be delivered to the tumor. This probe can be seen by the ultrasound device to guide the probe the proper location.

Immediate post-procedure

- Immediately following the procedure, you will be placed in a low-light area in the Clinical Research and Trials Unit (CRTU) to minimize side effects from the study drug. After 24 hours, you will be gradually exposed to more light. After 48 hours, you will be exposed to direct sunlight, and your reaction to sunlight will be assessed. If severe side effects are present, further stay in a low-light area will be required. During the two day stay, a physical exam and bloodwork will be done. On the second day after the procedure (Day 3), a CT scan will be done to assess the state of your tumors.

Post-procedure

- Two weeks after the procedure, you will return for another visit to have another physical performed, bloodwork done, and you will fill out the quality of life questionnaires.
- Following the two week visit, you will return 3 months, 6 months and one year after the date of the procedure to undergo a physical exam, bloodwork and a CT scan to assess the state of your tumors. If you are unable to return for visits you will be contacted by phone at these time-points and asked the Quality of Life questionnaire, if you have been hospitalized related to disease, progression of disease or any adverse events, this will take approximately 5 minutes.

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

Verteporfin Infusion and Photodynamic Therapy (PDT)
The major side effect of photodynamic therapy (PDT) with a verteporfin infusion is sensitivity to light. All patients who receive it will be sensitive to light for two to three days after the procedure. Because of this, you will spend the first day after the procedure in a room with very little light. Bright indoor light will be permitted after the initial one day period, but patients must observe precautions to avoid exposure of the eyes and skin to direct sunlight for at least two days. Patients who receive verteporfin can be safely exposed to sunlight only two days after sensitization. Some parts of your body may be more light sensitive than others.

Before going outside, you should test a small area of skin in the light for 10 minutes to make sure the effects of the drug have worn off. If you don't swell, get a rash or blisters within 24 hours, you can gradually resume normal outdoor activities, initially continuing to exercise caution and gradually allowing increased exposure. If a reaction occurs with the limited skin test, you should continue the existing precautions for another week before re-testing. Since the face is very sensitive, it is not recommended as a safe testing area. If you travel to a different geographical area with greater sunshine, you should retest your skin.

Sunscreen will not help prevent side effects, because visible light, not UV, causes them. For three days following treatment, you should wear dark sunglasses when outdoors, and should consult your ophthalmologist if they notice any change in vision after treatment. You will be given information on barrier protection (hat, gloves, long sleeves etc) and an emergency contact number will be given.

In addition to photosensitivity, you may experience a change in blood pressure due to the infusion. Abnormalities in blood tests related to the liver have been noted in up to 10% of patients receiving the study agent. Other potential side effects although rare include: pain, redness, swelling, or discoloration at the site of the injection, back pain during the infusion, dry eye, itchy eye, dry, itchy skin, constipation, nausea, muscle pain or weakness, decreased sensitivity to touch, or decreased hearing.

You will be monitored closely during and after the drug administration by the providing physician and study staff to ensure your safety. Many side effects go away shortly after phototherapy or verteporfin is stopped, but in some cases side effects can be serious, long lasting, or may never go away. There may be a risk of death. Some side effects may not be known. Side effects may range from mild to life-threatening. Other drugs may be given to make side effects less serious and less uncomfortable. Talk to the researcher and/or your healthcare provider about side effects and ask any other questions. You may also feel some slight discomfort at the site of the infusion; however this is normal and is resolved quickly.

Endoscopy
The risks of participating in this study are those that typically occur any endoscopic procedure using local anesthesia with sedation (allergic reaction to medications used, bruising or pain at the intravenous access site, hypoventilation) and the passing of an endoscope through the esophagus (difficulty or pain with swallowing, strictures in the throat, sore throat). The endoscopy itself may cause a cramping sensation in the stomach and you may feel bloated during the procedure because of air introduced into the stomach. The procedure is considered very safe, but it is possible to cause either bleeding or even a tear in the esophagus or stomach in rare (less than 1 in 1000) cases. Inflammation of the pancreas (pancreatitis) is possible rare complication which may require hospitalization for observation.

Antibiotics
The risks of taking oral antibiotics include stomach discomfort, nausea, photosensitivity and possible allergic reactions. You will be monitored for any of these reactions while you take the antibiotic.

CT Scans

CT uses X-rays to image the inside of your body. You will be exposed to additional radiation during the CT scans of your pancreas obtained for research. The amount of radiation you will receive has a low risk of harmful effects. Some people are given contrast material through a small tube inserted in their hand or arm, called receiving it intravenously or, "through an IV." Contrast material is an iodine-based substance that helps highlight the area that needs to be seen more clearly on the scan. Problems from receiving IV contrast material are rare. If you know you are allergic to contrast material, talk to the health care provider who ordered your CT scan. You may have an increased risk of having problems from IV contrast material if you have heart disease, asthma, diabetes, kidney problems or thyroid disease. You may be asked to drink two or more glasses of oral contrast material to highlight your digestive tract, or you may be given the contrast material as an enema. Rarely, people have an allergic reaction, stomach cramps or diarrhea from drinking the contrast material or receiving the enema. If you have had a CT scan before and had these symptoms, tell a radiology nurse before your scan.

Blood Draw

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

Pregnancy

The effects of the study drug on an unborn child are unknown. Because of this, if you are of childbearing potential, you will be required to undergo a pregnancy test before you enter the study. In addition to the pregnancy test, you will be required to use an adequate contraceptive method prior to entering the study and continue to use it for one week after the therapy.

Financial risk

Taking part in this research study may lead to added costs to you. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance company to see what services will be covered and what you will be responsible to pay.

Are there reasons you might leave this research study early?

You may decide to stop at any time. If you cannot tolerate the treatment, you can inform the study staff that you will not like to participate and your participation will be terminated.

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?

You may not directly benefit from taking part in this study. However, we hope that this study leads to quality of life improvements for you and future patients sharing your diagnosis.

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

If you choose not to participate in this study, your other option would be continuing your standard care.

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:

- Physical exams done for research
- The verteporfin infusion and PDT
- Physical exam
- Questionnaires
- All study related blood draws and pregnancy testing (if applicable)
- All study related CT scans
- The inpatient stay in the Clinical Trials Research Unit
- The endoscopy for the PDT

However, if there are other tests or procedures ordered by your physician, not related to this study or for incidental findings at the time of endoscopy 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. You will also be responsible for 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.

What will happen to your samples?

The only samples that will be collected for this study are blood samples. Your samples will be destroyed after analysis. The data collected from your samples will be shared with Massachusetts General Hospital and the National Institute of Health.

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 information will be stored either in a locked cabinet on the Mayo Clinic Campus, or on a password protected server.

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.

Health information may be collected about you from:

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

Why will this information be used and/or given to others?

- To do the research.
- To report the results.
- To see if the research was done correctly.

If the results of this study are made public, information that identifies you will not be used.

Who may use or share your health information?

- Mayo Clinic research staff involved in this study.
- Massachusetts General Hospital
- National Institute of Health researchers

With whom may your health information be shared?

- The Mayo Clinic Institutional Review Board that oversees the research.
- Other Mayo Clinic physicians involved in your clinical care.
- Researchers involved in this study at other institutions.
- 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.
- The sponsor(s) of this study and the people or groups it hires to help perform this research.
- A group that oversees the data (study information) and safety of this research.

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 Privacy Rights

You do not have to sign this form, but if you do not, you cannot take part in this research study.

If you cancel your permission 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.

If you choose not to take part or if you withdraw from this study, it will not harm your relationship with your own doctors or with Mayo Clinic.

You can cancel your permission 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
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 lasts until the end of this study, unless you cancel it.

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ENROLLMENT AND PERMISSION SIGNATURES

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

	/ /	: AM/PM
Printed Name	Date	Time

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.

	/ /	: AM/PM
Printed Name	Date	Time

Signature