Window Trial of Fluorescently Labeled Panitumumab (Panitumumab-IRDye800) in Head and Neck Cancer

NCT06819228

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Study Title: Window Trial of Fluorescently Labeled Panitumumab (Pan800) In Head and Neck Squamous Cell Carcinoma (HNSCC)
Version Date: August 5, 2025
PI: Eben Rosenthal, MD

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

General Information	You are invited to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of the study is to determine the dose of panitumumab that reaches maximum tumor concentration (MTC) in patients with head and neck squamous cell carcinoma (HNSCC) that will undergo standard of care head and neck cancer surgery.
Overview of Procedures	If you agree to enroll, you will receive infusions of panitumumab and panitumumab-IRDye800 prior to your surgery. You will be evaluated for any reactions to the drug immediately after the injection, before your surgery, and up to 30 days after your infusion.
Risks	The most likely risks are infusion reactions, rash, dry or itchy skin, fatigue, decreased magnesium and/or other minerals in your blood.
Benefits	You may or may not have a direct benefit from being in the study. Study doctors hope to be able to use the information on the safety of the study drug to help treat future cancer patients.

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Alternatives

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, please tell the Protocol Director or a member of the research team.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because you have been diagnosed with head and neck cancer and plan to undergo surgery with curative intent, meaning the intent of your planned surgery is to remove all of cancer if possible.

We are exploring the use of panitumumab in Head and Neck Cancer. Panitumumab is an approved drug named Vectibix® and is used as an anti-cancer agent in other cancers such as colorectal cancer. It works by attaching to the cancer cell in a unique way that allows the drug to get into the cancer tissue. In addition to the panitumumab, you will also receive a panitumumab-IRDye800 (pan800, or fluorescently labeled panitumumab) infusion. IRDye800 is an investigational dye that, when tested in the lab, helps various characteristics of human tissue show up better when using a special camera during surgery. Panitumumab-IRDye800 is a combination of the drug and the dye that attaches to cancer cells and appears to make them visible to your doctor when he or she uses the special camera during your surgery.

The goal of this study is to use a novel and possibly safer approach to identify an optimal dose for panitumumab to treat cancer patients by using a new light-based therapy. We plan to enroll 18 participants. In this study, we will monitor different drug levels using this approach to understand how much drug reaches the tumor at different administered doses, which may help us provide safer and/or more effective therapies in the future.

In this study, we are researching to identify the correct amount or dose of a drug that is needed for effective cancer therapies. Often, clinical studies look at how much of the drug can be tolerated before patients become sick, rather than how much of the drug is required to be effective.

IRDye800 is an investigational dye that helps various characteristics of human tissue show up better when using a special camera during surgery. Panitumumab-IRDye800 is a combination of the drug and the dye that attaches to cancer cells and appears to make them visible to your doctor when he or she uses the

special camera during your surgery. This will help the surgeon with clinical margins during surgery and may have a clearer way to differentiate between cancer and healthy tissue.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record may also get this information.

Side effects and risks that you can expect if you take part in this study:
There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director or study team if you have any questions.

Panitumumab-IRDye800
The study drug has been tested in humans before. During the Phase I trials with this drug, no patients experienced clinical symptoms or side effects; however, this is still an experimental drug, meaning it is not approved by the FDA for treatment of this condition. We do not expect that the pan800 will cause an increased chance of side effects from unlabeled panitumumab, however, this is not known for sure.

Despite extensive efforts to ensure your safety, other unexpected side effects could occur. In animal studies, there were heart rhythm changes during the infusion – however, the animals did not experience any clinical symptoms during the infusion or during the monitoring period for 2 weeks after the infusion. These heart rhythm changes are abnormal heart rhythms and could indicate serious effects resulting in death.

Potential Risks of Panitumumab (VECTIBIX®)
Panitumumab-IRDye800 contains the panitumumab antibody. Panitumumab is approved by the US FDA for treatment of certain types of advanced colorectal cancer at a dosage of 6 mg/kg given every 14 days. Many of the reported risks are associated with repeat administration of panitumumab.

The most common side effects patients have experienced when receiving panitumumab primarily include skin reactions (including acne like rash, dry or itchy skin, cracking of skin around your nail beds, skin infections, and dry eyes), fatigue, nausea, and diarrhea. Monitor skin reactions carefully to prevent serious or life-threatening complications. Exposure to sunlight may make skin reactions worse; limit exposure by using sunscreen and protective clothing.

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Infusion reactions, including fever, chills, difficulty or labored breathing, and low blood pressure, occurred in 4% of patients taking panitumumab. These reactions are most likely during or immediately following panitumumab infusion. Severe infusion reactions occurred in 1% of patients. Based on your study doctor's routine practice, he or she may decide to give other drugs, such as an antihistamine called diphenhydramine (Benadryl) or steroids, if it's felt necessary to treat a reaction. **Tell your doctor, nurse, or study team member immediately if you experience any of the symptoms of an infusion reaction.**

Patients receiving repeated doses of panitumumab occasionally had progressively decreased magnesium and/or other minerals in the blood. Your blood chemistry levels will be monitored closely during this study, and electrolyte replacement will be given if necessary.

There have been rare reports of patients experiencing both fatal and non-fatal lung disease after treatment with panitumumab. You should notify your study doctor if you have ever had lung disease. **Notify a study team member immediately if you experience sudden or worsening breathing troubles.**

Potential Reproductive Risks

Women of Childbearing Potential

Based on data from animal studies, panitumumab may cause fetal harm (organ damage or death) if administered to pregnant women. If you or your partner are able to become pregnant, it is strongly encouraged that you will either use an effective method of birth control and/or abstain from sexual intercourse during study participation and for at least 2 months after the final dose of the study drug to prevent exposing a fetus to a potentially dangerous agent with unknown risk.

If you are currently pregnant or breastfeeding, you may not participate in this study. You understand that if you are pregnant, if you become pregnant, or if you are breastfeeding during this study, you and/or your child may be exposed to an unknown risk.

Potential Study Procedure Risks

Blood Draw: Inserting an IV catheter or needle into your arm for drawing blood, may cause slight discomfort or bruising at the puncture site. Lightheadedness or fainting may occur. Rarely, an infection at the puncture site may occur.

ECG: The adhesive pads used during this procedure may cause mild skin irritation or may cause discomfort if there is body hair that is pulled out when the electrode pads are removed. To prevent this, you may shave your chest area or ask the nurse to do this for you.

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Risks that are not known:
Because this treatment is investigational, meaning non-FDA approved, there may be risks that we do not know about at this time.

Good effects that might result from this study:
You may not benefit directly from taking part in this study. However, information obtained from your participation in this study may benefit other people with cancer in the future and help evaluate detection of undetected disease during primary tumor removal using an infusion of panitumumab-IRDye800 prior to surgery compared to standard of care procedures for tumor detection.

From this study, we also hope that the results of this study will help improve dose selection for future oncologic therapies to help minimize side effects and financial burden to patients.

We cannot and do not guarantee or promise that you will receive any benefits from this study.

Procedures to be followed:
If you choose to participate in this study, Dr. Eben Rosenthal and his research team will perform the procedures listed below in addition to your normal pre-operative, surgery, and follow-up clinic visits and examinations.

Please refer to **Table 1a or 1b below for procedures that will be followed.**

Screening Period
If you choose to volunteer to participate in the study and sign this consent form, you will undergo the following assessments to determine if you are eligible to take part in this study. If you have already had some of these procedures recently, they may not need to be repeated. The screening period will last no more than 30 days.

The following assessments will occur during screening:

- Review your medical history and current medications.
- Physical exam, including height, weight, and vital signs (blood pressure, heart rate, respiratory rate, and temperature).
- Performance status – a measure of how you are feeling.

- Electrocardiogram (ECG) – a test to measure and record the electrical activity of your heart. Sticky pads (electrodes) will be placed at different points on your body, you will be asked to lie still while the machine records your heart activity.
- Blood draw for lab safety tests (approximately 2 teaspoons).
- Pregnancy test, if applicable (approximately ½ teaspoon of blood).

Study Drug Infusion
This study contains multiple cohorts, or dosing groups. Your group depends on the timing of your enrollment. If you meet all the eligibility requirements to participate, participants in Cohort 1 will receive their infusions of panitumumab and pan800 approximately 1-4 days prior to your scheduled surgery date.

Participants in Cohort 2 will receive an extra dose of panitumumab approximately 14 days prior to your scheduled surgery and then another infusion of panitumumab and pan800 approximately 1-4 days prior to your scheduled surgery.

	Infusion ~2 weeks before Surgery Panitumumab	**Infusion 1-4 Days before Surgery Panitumumab + Pan800**
Cohort 1		X
Cohort 2	X	X

All procedures will occur at the main campus. The following procedures will occur:

Prior to the infusion:
- Record vital signs.
- Complete a physical exam from a study doctor.
- Review any current medications.
- Blood draw for lab safety tests and research testing (approximately 2 teaspoons).
- Record any side effects.

Administration of panitumumab-IRDye800 and panitumumab: The pan800 infusion will be given one time over 15 minutes through an IV line via a vein in your arm. You will be observed for approximately 30 minutes following the end of the pan800 infusion and vital signs will be recorded. If no complications occur, panitumumab will be administered over 60 minutes.

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Observation (60 minutes): Safety monitoring for approximately 60 minutes after the end of the second infusion to monitor for side effects or reactions. Your study doctor may prescribe other medications to treat or prevent side effects**. At any time during the infusions, it is important for you to let the research team know if you experience anything that does not feel normal.**

Day of Surgery
You will have the same surgery you would receive if you were not part of a research study. The details of this surgery will be part of your regular medical care and will be determined by your surgeon based on your medical condition.

On the day of surgery, the following procedures will occur for study purposes:

- Surgical imaging and resection of cancer tissue
  - Before and after the surgeon has removed as much cancer as per the surgical plan using standard methods, the investigator will use special cameras (fluorescence cameras) to take images of the tumor.
  - Before and after the surgeon has removed any lymph nodes from the neck per the surgical plan using standard methods, the investigator will use special cameras (fluorescence cameras) to take images of the lymph nodes for the study.
- Pathology evaluations – after removal of the tumor and lymph node tissues will be sent to the pathology laboratory as standard practice.

The research imaging and evaluations will not affect the routine diagnostic pathology tests that will be performed on your tissues.

Day 1,2, 3 and/or 4 Post-Surgery
While you are in the hospital a blood sample will be obtained to measure pan800 antibodies in your blood.

Follow-Up
You will be asked to return to clinic approximately 15-30 days following your day of surgery and the following procedures will occur. Whenever possible, we will coordinate this visit with your routine follow-up visit with your surgeon so that you will not necessarily have any additional visits.

- Physical exam, including height, weight, and vital signs (blood pressure, heart rate, respiratory rate, and temperature).
- ECG only if indicated.
- Blood draw for lab safety tests and research testing (approximately 2 teaspoons).
- Record any side effects.

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Table 1a: Study Calendar (Participants in Cohort 1)

Study Visit / Procedures	Screening/Pre-Treatment (~30 Days Before Infusion)	Infusion – Pan + Pan800 (1-4 Days Pre-op)	Day Of Surgery Day 0	Follow-Up Day 30 (± 14 days)
Written informed consent	X			
Tumor tissue sample	X		X	
Demographic data	X			
Medical history and baseline conditions	X			
Vital signs	X	X	X	X
Complete physical examination	X			X
Limited physical examination		X		
ECOG performance status	X			
12-lead ECG	X	X		X**
CBC w/ diff	X	X*		
Chemistry	X	X*		
Magnesium/Phosphorus	X	X*		
Pregnancy test	X	X***		
Panitumumab infusion		X		
pan800 infusion		X		
Concomitant medication	X	X		X
AE assessment	X	X		X
Blood sample for pharmacokinetics	X	X	X	X
Blood sample for immunogenicity		X		X

* Lab values will be redrawn only if the results are reported more than 30 days from the first infusion visit.
** ECG at follow-up will only be completed if indicated after the infusion visit.
*** Pregnancy test, either urine or serum, is required for any participant of childbearing potential within 14 days of infusion.

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Table 1b: Study Calendar (Cohort 2 only)

Study Visit / Procedures	Screening/Pre-Treatment (~30 Days Before Infusion)	Cohort 2 (Only) (~2 weeks before surgery)	Infusion – Pan + Pan800 (1-4 Days Pre-op)	Day Of Surgery Day 0	Follow-Up Day 30 (± 14 days)
Written informed consent	X				
Tumor tissue sample	X			X	
Demographic data	X				
Medical history and baseline conditions	X				
Vital signs	X	X	X	X	X
Complete physical examination	X				X
Limited physical examination		X	X		
ECOG performance status	X				
12-lead ECG	X	X	X		X**
CBC w/ diff	X	X*	X*		
Chemistry	X	X*	X*		
Magnesium/Phosphorus	X	X*	X*		
Pregnancy test	X				
Panitumumab infusion		X	X		
pan800 infusion			X		
Concomitant medication	X	X	X		X
AE assessment	X	X	X		X
Blood sample for pharmacokinetics	X	X	X	X	X
Blood sample for immunogenicity		X			X

* Lab values will be redrawn only if the results are reported more than 30 days from the first infusion visit and prior to secondary infusion for Cohort 2,
** ECG at follow-up will only be completed if indicated after the infusion visit(s).
*** Pregnancy test, either urine or serum, is required for any participant of childbearing potential within 14 days of infusion.

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Specimen Storage for Future Research
Research using human specimens is an important way to try to understand human disease. You have been given this information because the investigators will save your specimens including oral swabs, blood, and tissue for future research if they are available from your standard of care and as standard of procedure for the Head and Neck Repository. There are several things we would like you to be informed about.

Your specimens and any data collected as part of this study will be stored in the Head and Neck Biorepository (IRB# 030062) at Vanderbilt University Medical Center (VUMC). Samples will be labeled with a study ID code number that does not personally identify you.

The key linking the study ID code with your personal information will not be shared with researchers. Your samples may be sent outside of VUMC for research and analysis. Identifiers will be removed from identifiable private information and/or identifiable specimens, and, after such removal, the information and/or specimens could be used for future research studies or distributed to investigators within or outside VUMC for future research studies without additional informed consent from you.

Saving Images for Future Research
Investigators would like to save the images and data from your fluorescence imaging along with surgery images for future research projects. Your data will be de-identified (removing your name and medical record number), coded for confidentiality, and stored at VUMC in a secure, password protected computer. Your name and other personal identifiers will not be included in any data shared with other researchers. Your images may be sent outside of VUMC for research and analysis.

Payments for your time spent taking part in this study or expenses:
You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study however, you will not be paid if you are a resident of a country restricted by the U.S. government's comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid.

You will be paid to participate in this research study. You may receive up to a total of $100 if you complete this study.

If you do not complete the study, for any reason, you will be paid for each study visit you do complete. We will complete a check request for you via Vanderbilt's Finance Department at the end of your

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participation. The check may take 4-6 weeks to process. We may ask you for your Social Security number and address on a form before you are compensated for taking part in the study. You may also receive travel reimbursement up to $600 total with appropriate receipts and/or documentation to study team.

If you have any questions regarding your compensation for participation and/or travel reimbursement, please contact the study staff.

Costs to you if you take part in this study:
If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator, Dr. Eben Rosenthal, that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt, or Dr. Eben Rosenthal, to pay for the costs of any additional care. There are no plans for Vanderbilt or Dr. Eben Rosenthal to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Eben Rosenthal at (615) 936-0708. Your Study Coordinator will also provide you with contact information. If you cannot reach the research staff, please page the study doctor by calling (615) 322-5000 and ask the operator to page him.

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For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Human Research Protections Program at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
The Protocol Director may also withdraw you from the study and administration of the study agent may be stopped without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- Pregnancy
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

What will happen if you decide to stop being in this study?
If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you withdraw from the study, or administration of the study agent is stopped for any reason, you will be asked to return to the clinic approximately one month from Day 0 for a safety follow up appointment (will be coordinated where possible with a routine visit).

Clinical Trials Registry:
A description of this clinical trial will be available on 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 Web site at any time.

Confidentiality:
The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law. However, there is always some risk that even de-identified information might be re-identified.

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Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study, future research, or insurance purposes. Disclosures that you make yourself are also not protected.

Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Your samples may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

At any time, you may ask to have your sample destroyed. You should contact Eben Rosenthal at (615) 936-0708 to have your sample destroyed and no longer used for research. We will not be able to destroy research data that has already been gathered using your sample. Also, if your coded identity was removed from the samples, we will not be able to locate and destroy them.

There will be no costs to you for any of the tests done on your samples for research purposes. You will not be paid for the use of your samples.

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Study Results:
The research results will be shared with you by request when the study is closed out. The shared study results may include peer-reviewed scientific publications, news releases, and clinical trials reports at ClinicalTrials.gov.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers, insurance providers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

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What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

Eben Rosenthal, MD
Vanderbilt University Medical Center
Suite 6310, Medical Center East, South Tower
1215 21st Avenue South
Nashville, TN 37232

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

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STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

_____ _____
Date Signature of patient/volunteer

_____ _____
Date Signature

_____
Printed Name and Title