More Than Minimal Risk
Consent and HIPAA Form

Principal Investigator	Malcolm Mattes, MD
Department	Radiation Oncology
Protocol Number	WVU 011118
Study Title	Measurement of the Partial Pressure of Oxygen in Cutaneous Tumors Using Electron Paramagnetic Resonance Oximetry
Lay Title	Measurement of oxygen in cancers of the skin
Co-Investigator(s)	Valery Khramtsov, PhD; Mark Tseytlin, PhD; Oksana Tseytlin, MS; Andrey Bobko, PhD; Timothy Eubank, PhD; Raymond Raylman, PhD; Sally Hodder, PhD; Geraldine Jacobson, MD; Kayla Steinberger, BS; Michael Kolodney, MD, PhD; Min Deng, MD; Rusha Patel, MD; Alan Thomay, MD; Mohammed Almubarak, MD; Miklos Auber, MD; Michael Craig, MD; Thomas Hogan, MD; Abrahan Kanate, MD; Joanna Kolodney, MD; Sobha Kurian, MD; Patrick Ma, MD; Inderjit Mehmi, MD; Shalu Pahuja, MD; Aaron Provenzano, DO; Kelly Ross, MD; Mohamad Salkeni, MD; Nilay Shah, MD
Sponsor	WVU Cancer Institute Mary Babb Randolph Cancer Center

Contact Persons

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In the event you experience any side effects or injury related to this research, you should contact Dr. Mattes at (304) 598-4706. After hours, contact the Radiation Oncology Doctor on call at (304-598-4000). If you have any questions, concerns, or complaints about this research, you can contact Dr. Mattes (304)-598-4706.

For information regarding your rights as a research subject, to discuss problems, concerns, or suggestions related to the research, to obtain information or offer input about the research, contact the Office of Research Compliance at (304) 293-7073.

In addition if you would like to discuss problems, concerns, have suggestions related to research, or would like to offer input about the research, contact the Office of Research Integrity and Compliance at 304-293-7073.

Introduction

You, _____, have been asked to participate in this research study, which has been explained to you by _____. This study is being conducted by Dr. Malcolm Mattes in the Department of Radiation Oncology at West Virginia University with funding provided by the West Virginia Clinical and Translational Science Institute.

Purpose of the Study

It has been explained to you that you have a malignant tumor involving the skin. You have been invited to participate in this research study, which involves taking at least one measurement of the oxygen level in this tumor before, during, and after breathing oxygen through a facemask. The goal of the measurements is to learn more about changes in tumor oxygen levels in response to breathing extra oxygen, as well as standard treatments like chemotherapy and radiation therapy, so that in the future we have a better understanding of how to best use these treatments to improve their ability to fight cancer. These measurements will in no way effect the treatment you receive for your cancer, and there is no experimental treatment associated with this study.

Description of Procedures

All patients enrolled in this study will undergo two initial measurements of their tumor oxygen level. These measurements will be carried out on the ground floor of the Erma Byrd Biomedical Research Center at WVU. This building connects to the cancer center, and a member of our staff will help you find its location. On the first day, you will first have a small metal disc (less than 1 cm in diameter) called a SPOTChip placed on the surface of your tumor, and held in place using an adhesive. You will then be positioned (lying down or sitting) between a set of two magnets that are used to measure the oxygen level in the tumor. A small plastic oxygen-detector will be placed on your skin over your tumor. We will use these devices to take a measurement of your tumor's oxygen level at baseline, then while breathing oxygen through a clear plastic facemask, and then a final time after the oxygen facemask has been removed. Overall the measurements should take approximately 45-60 minutes. We will ask you to move around as little as possible during the measurements. You will also have a small sensor (pulse oximeter) on your finger during this period to measure the oxygen in your blood. After we take these measurements, we will inject a small amount (20-50 microliters) of India ink into your tumor using a small (28-gauge) needle. The India ink used in this study is made of purified charcoal,

gum arabic, and saline. It is commonly used for medical marking and tattoos. The India ink will make a permanent, dark blue/black colored mark on your tumor. This mark is usually the size of a pencil eraser but may sometimes be slightly smaller or larger. The ink leaves a permanent tattoo in the spot where it is injected, unless it is physically removed surgically.

We will ask you to return for another measurement, at least 2 days later. This measurement will use the India ink that was previously injected (described above) and you will no longer need to use the SPOTChip. For the India ink tumor oxygen measurement a small piece of wire (called a loop resonator) will be placed over the tumor and held in place using medical honey and saran wrap or tape. We will first take a measurement of your tumor's oxygen level at baseline, then while breathing oxygen through a clear plastic facemask, and then we will take off the mask and measure your tumor's oxygen level as it returns to baseline. Overall the measurements should take approximately 45-60 minutes in total, and we will ask you to move around as little as possible during the measurements. You will also have a small sensor (pulse oximeter) on your finger during this period to measure the oxygen in your blood.

If your plan of treatment involves surgical excision of your tumor, there will be no further measurements after this point and your involvement in this trial will be complete. If your tumor is being treated with radiation therapy, we will ask you to come back for weekly measurements of your tumor during treatment, followed by one additional measurement one month after you complete the course of radiation therapy. If your tumor is being treated with chemotherapy or other medical therapies without radiation, we will ask you to come back for measurements every 3-4 weeks on the day you receive your regular infusion, followed by one additional measurement one month after you complete the course of medical therapy.

There are anticipated circumstances under which your participation may be stopped by the investigator without regard to your consent, particularly if your physician determines that continuing the measurements is not in your best interest. You may also withdraw from the study at any time.

Risks and Discomforts

EPR oximetry has no adverse health effects for most people. However, it does use magnetic fields, and if you have any type of electrically, magnetically, or mechanically activated implants you should not participate in this study. This includes certain medical devices such as implanted pacemakers, defibrillators, neurostimulators, portable infusion pumps, and cochlear implants. Additionally, you should not participate in this study if you have a metallic foreign body located in your head or eye. The magnetic field also may involve risks to an unborn child. For this reason, women who are pregnant will not be accepted in this study. If you are a woman who could become pregnant, you will not be allowed to participate in this study until you have had a pregnancy test and the test has indicated that you are not pregnant. Women who could become pregnant must use a medically approved method of birth control while you are on this study. For all other patients, the measurement itself is non-invasive and non-painful. Other possible risks may include anxiety or stress,

claustrophobia, or discomfort due to positioning. Heating of the skin is theoretically possible but is very unlikely.

India ink injection also has minimal risk. There may be some brief discomfort, pain or bleeding from the injection, though these side effects are uncommon. The India ink will affect the appearance of your skin, as it leaves a permanent mark/tattoo in the injected tumor. It is possible to experience an allergy to the India ink, particularly the gum arabic. However, if your tumor is surgically removed after the India ink injection, the ink is removed with the tumor. It is theoretically possible, but considered extremely unlikely, that injection of the tumor with India ink could cause the tumor to spread outside of its current location in the skin. Finally, the India ink may cause a false positive result on a PET/CT scan should you have this imaging test in the future. There is no known increased risk of your tumor spreading as a result of the India ink injection.

Use of the SPOTChip may result in discomfort or pain associated with removal of the adhesive material, much like the removal of a large bandage. There is also the risk of allergic reaction to the adhesive used. Breathing oxygen through a facemask may cause a feeling of dryness in your mouth or nostrils or discomfort from wearing the facemask.

Alternatives

You do not have to participate in this study. Participation in this study is voluntary. You are free to withdraw your consent to participate in this study at any time. Refusal to participate or withdrawal will involve no penalty to you and will not affect your future care, or your employee status, if applicable, at West Virginia University. The alternative to participating in this trial is to receive standard of care treatment for your cancer as recommended by your physicians, without any measurements of tumor oxygen levels.

Benefits

This trial will not impact your treatment in any way. For this reason, your participation is not expected to improve your health.. The knowledge gained from this study may eventually benefit others.

Financial Considerations

The cost of the all materials, personnel, and equipment used in this study will be covered by the study sponsor. No aspect of this study will be billed to your insurance company. The standard of care treatment you undergo for your cancer will be billed to your insurance company in the same way as if you did not participate in this trial. There may be some additional expenses related to this study, such as transportation, parking, or meals. To compensate you for your time a $30 gas or grocery card will be offered to you every time you come to the EPR center for an oxygen measurement.

Voluntary Compensation

If you are injured as a result of this research, treatment will be available. Responsibility for this treatment will be borne by you and/or your insurance company. In the event that you are physically injured as a result of participating in this research, care will be available. You will, however, be responsible for the charges for the care. There is no commitment to provide any compensation for research-related injury. You should realize, however, that you have not released this institution from liability for negligence. Please contact the investigator, Dr. Malcolm Mattes at 304-598-4706 if you are injured or for further information.

Confidentiality

Any information about you that is obtained as a result of your participation in this research will be kept as confidential as legally possible. Your research records and test results, just like hospital records, may be subpoenaed by court order or may be inspected by the study sponsor or federal regulatory authorities (including the FDA if applicable) without your additional consent.

In addition, there are certain instances where the researcher is legally required to give information to the appropriate authorities. These would include mandatory reporting of infectious diseases, mandatory reporting of information about behavior that is imminently dangerous to your child or to others, such as suicide, child abuse, etc.

In any publications that result from this research, neither your name nor any information from which you might be identified will be published without your consent.

HIPAA

We know that information about you and your health is private. We are dedicated to protecting the privacy of that information. Because of this promise, we must get your written authorization (permission) before we may use or disclose your protected health information or share it with others for research purposes.
You can decide to sign or not to sign this authorization section. However, if you choose not to sign this authorization, you will not be able to take part in the research study. Whatever choice you make about this research study will not have an effect on your access to medical care.

Persons/Organizations Providing the Information

- Patient/West Virginia University Medicine

Persons/Organizations Receiving the Information

- The research site(s) carrying out this study. This includes UHA or UHA Affiliated, WVU, WVU Medicine, or the covered entities under the purview of West Virginia University, collaborating institutions, affiliate institutions, and component institutions. It also includes each site's research staff and medical staff.
- Health care providers who provide services to you as part of this research study.

- Laboratories and other people and groups that look into your health information as part of this study in agreement with the study protocol.
- The United State Department of Health and Human Services (which includes the National Institutes of Health (NIH), Food and Drug Administration (FDA)) and other groups that have the right to use the information as required by law.
- The members and staff of any Institutional Review Board (IRB) that oversees this research study.
- West Virginia University Office of Research Compliance and Office of Sponsored Programs.
- West Virginia University Clinical Trials Research Unit.

The Following Information Will Be Used

- Information from your existing medical records and new information about you that is created or collected during the study such as: history and physicals, clinic visit notes, nursing and staff notes, laboratory results, x-rays, EKG results, demographic data, pulmonary tests, imaging scans and study forms.

The Information is Being Disclosed for the Following Reasons

- Review of your data for quality assurance purposes
- Publication of study results (without identifying you)
- Other research purposes such as reviewing the safety or effectiveness of the study drug and other products or therapies; conducting performance reviews of the study drug; evaluating other products or therapies for patients; developing a better understanding of disease; improving the design of future clinical trials

You May Cancel this Authorization at Any Time by Writing to the Principal Investigator

Malcolm Mattes, MD
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1 Medical Center Drive, PO Box 9234
Morgantown, WV 26506

If you cancel this authorization, any information that was collected already for this study cannot be withdrawn. Once information is disclosed, according to this authorization, the recipient may re-disclose it and then the information may no longer be protected by federal regulations.

You have a right to see and make copies of your medical records. You will not be able to see or copy your records related to the study until the sponsor has completed all work related to the study. At that

time you may ask to see the study doctor's files related to your participation in the study and have the study doctor correct any information about you that is wrong.

This authorization will expire at the end of the study unless you cancel it before that time.

Voluntary Participation

Participation in this study is voluntary. You are free to withdraw your consent to participate in this study at any time.

Refusal to participate or withdrawal will involve no penalty to you. Refusal to participate or withdrawal will not affect your future care, or your employee status at West Virginia University.

In the event new information becomes available that may affect your willingness to participate in this study, this information will be given to you so that you can make an informed decision about whether or not to continue your participation.

You have been given the opportunity to ask questions about the research, and you have received answers concerning areas you did not understand.

Upon signing this form, you will receive a copy.

I willingly consent to participate in this research.

Signature of Subject of Subject's Legal Representative	Printed Name	Date	Time

The participant has had the opportunity to have questions addressed. The participant willingly agrees to be in the study.

Signature of Investigator or Co-Investigator	Printed Name	Date	Time