Official Title: Correlation of Vascular Endothelial Growth Factor Levels in Anterior Chamber Fluid to Disease State in Patients With Retinal Vein Occlusion Receiving Standard of Care Treatment
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Wake Forest School of Medicine

INFORMED CONSENT

TITLE: CORRELATION OF VASCULAR ENDOTHELIAL GROWTH FACTOR LEVELS IN ANTERIOR CHAMBER FLUID TO DISEASE STATE IN PATIENTS WITH RETINAL VEIN OCCLUSION RECEIVING STANDARD OF CARE TREATMENT

Informed Consent Form to Participate in Research

Principle Investigator: Mark Nelson, MD, MBA

Co-Investigator: Sally Ong, MD

Co-Investigator: Rebecca Sappington, PhD

Co-Investigator: Joseph Rigdon, PhD

Site Address: [redacted]

Site Phone Number: [redacted]

Summary

You are invited to participate in a research study since you were found to have a Retinal Vein Occlusion (RVO). This condition has led to vision loss. It is due to a blockage of the vein or blood vessel that takes blood out of the retina which is the lining in the back of the eye. This blockage has led to leakage and vision loss due to edema or thickening of the retina, specifically the macula which is centrally located and responsible for all reading vision.

The purpose of this research is to measure different chemicals that are found in the eyes of patients with RVO. Vascular Endothelial Growth Factor (VEGF) is a chemical that is over produced in your eye due to the RVO and leads to macular edema (swelling of the retina) and vision loss. This research project

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will specifically measure the level of VEGF. The measurement of VEGF is done through removing a small amount of fluid from your eye prior to an intravitreal injection. The removal of this fluid is being done as part of routine care and would normally be discarded. Participation in this study will allow the researchers to keep and analyze the fluid removed from your eye and access some information from your medical record.

Your participation in this study is voluntary. You do not have to participate in this study. You should talk to your doctor about all the choices you have. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Dr. Mark Nelson (Principal Investigator, PI). If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, the contact information is:

Dr. Mark Nelson - Principal Investigator

[redacted]

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

Introduction

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have a retinal vein occlusion (RVO) . Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

Why Is This Study Being Done?

The purpose of this research study is to measure the levels of Vascular Endothelial Growth Factor (VEGF) which is a protein over produced in the eye in patients who have RVO, and which causes the macular (central part of the retina responsible for reading vision) edema that is responsible for vision loss. The drugs that we use today to treat RVO are VEGF blocking drugs, or anti-VEGF drugs, which prevents VEGF from being made. We can measure the level of VEGF in the eye with a research test, ELISA, that is done in a laboratory and not available to the doctor treating you. By measuring VEGF, we will be able to predict the amount, rate, and type of drug necessary to treat you. This study mainly focuses on VEGF. There are other proteins that are similar to VEGF because they cause abnormal blood vessels to grow and leak and there are proteins that are related to inflammation or a body reaction to disease. However, at this time, VEGF will be the only protein studied and the samples will be frozen, saved, and evaluated later.

The removal of fluid from the eye is standard of care prior to getting an intravitreal injection. The only thing that is investigational in this study is to take the fluid and measure it as opposed to discarding it.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

20 people at Wake Forest Baptist Health Highland Oaks will take part in this study.

What Is Involved in the Study?

Screening period: You will be asked to read this Informed Consent Form, or if you are unable to read due to low vision, it will be read to you. If you agree to participate in this study, you will sign this consent before any study-related activities are started.

A paracentesis will be performed after topical anesthetic or numbing is given. In a small number of patients, a small amount of anesthetic will be given with an injection for additional comfort, if requested. The paracentesis will remove a small amount of fluid from the front part of the eye. This fluid contains VEGF which will be the sample to determine the VEGF levels in your eye. A paracentesis will be performed at every study visit prior to anti-VEGF treatment. During this procedure a syringe will be placed into the front part of the eye, and 0.1ml (approximately 3 drops) of fluid will be removed from the anterior chamber section of the eye, or the space between the iris and cornea. The fluid that is removed from the eye will be stored and saved for testing. After the numbing, a drop of iodine will be used to clean the area of the eye that will be injected including the skin around your eye. A lid speculum (device to keep the eye open) will be inserted under your eyelids to keep your eye open during the procedure.

How Long Will I Be in the Study?

You will be in the study for 12 months.

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about how leaving the study will not mean that you have to stop anti-VEGF injections. However, Dr. Nelson will tell you that vision loss will continue if you decide the stop all anti-VEGF injections at any time.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you (as outlined below). You should discuss the risk of being in this study with the study staff.

There is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. The measurements of the VEGF will be stored on Wake computers and no one outside of Wake Forest will have access to these numbers. The samples of fluid will be de-identified or the names will be replaced with numbers. Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe. We do ask permission to allow the measurements of all the study participants together be studied and be used in applications for research grants (funding). Again, it must be emphasized that individual information, for example your specific measurements, will not be shared

There also may be other risks that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

Are There Benefits to Taking Part in the Study?

If you agree to take part in this study, there will be no direct benefit to you. We hope the information learned from this study will benefit other people in the future.

What Other Choices Are There?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have.

What Are the Costs?

Neither you nor your insurance company will be billed for any cost associated with the analysis of the VEGF. You and/or your insurance company will be billed for the cost of the intravitreal injection, the cost

of the anti-VEGF medications, and the cost of the eye exam and any other procedures needed to treat your RVO and follow their rules for deductible and copays. Costs for your regular medical care, which are not related to this study, will be you or your insurance company's responsibility.

Will Your Research Records be Confidential?

Protected Health Information (PHI) will include patient demographics and clinical data that will be entered into EPIC. The anterior chamber fluid samples will be de-identified in the Highland Oaks office prior to sending the samples to Dr. Sappington's lab. These measurements will not be added to EPIC and will be kept in securely at Highland Oaks and Dr. Sappington's lab.

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 because individual data will be deindentified or given a number without your name. We are asking for permission to send the data to two outside organizations that are applying for a Federal Research Grant (SBIR). The two organizations are a company in North Carolina that is trying to make a medical device that can measure these study proteins quickly and the other company is a research company created years ago by Dr. Mark Nelson dedicated to bringing the medical science and commercial industries together. There is always some risk that even de-identified information might be re-identified.

Will You Be Paid for Participating?

You will receive no payment or other compensation for taking part in this study. The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

Who is Sponsoring this Study?

This study is being sponsored by Wake Forest University Health Science, Department of Ophthalmology. The researchers do not, however, hold a financial interest with respect to this study.

What About My Health Information?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health is considered Protected Health Information. The information we will collect for this research study includes VEGF levels during the course of your anti-VEGF treatment and this numbers will not be placed into EPIC.

If this research study involves the diagnosis of treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and will be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups, it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified.

You can tell Dr. Mark Nelson that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Dr. Mark Nelson – Principle Investigator

[redacted]

[redacted]

[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

Whom Do I Call if I Have Questions or Problems?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Mark Nelson, Wake Forest Baptist Health Highland Oaks at [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this signed consent form.

Signatures

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature:_____

Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____

Date: _____ Time: _____ am pm