VUMC Institutional Review Board
Informed Consent Document for Research

Study Title: Effect of Artificial Tears on Radioiodine Levels in the Nasolacrimal Duct System of Patients Following Radioiodine Therapy for Thyroid Carcinoma

Version Date: 1/7/2022

PI: Dr. Rachel Sobel NCT04327999

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:

Instructions:

Radioactive iodine therapy for thyroid carcinoma has been associated with nasolacrimal duct obstruction (blocked tear duct). There are currently no interventions to decrease the risk of developing radioactive iodine associated nasolacrimal duct obstruction. This study aims to identify a potential preventative measure for decreasing the incidence of developing nasolacrimal duct obstruction after radioactive iodine therapy through the use of artificial tears. The theory is that the artificial tears will dilute the amount of radioactive iodine in the tears of the eyes, thus decreasing uptake by the cells lining the nasolacrimal duct system. The study involves administration of preservative-free artificial tears to the right eye without administration of artificial tears into the left eye for four days after administration of radioactive iodine therapy.

The participant may benefit from the study by decreasing the risk of developing nasolacrimal duct obstruction in the study eye receiving artificial tears.

The study requires that the patient receive routine radioactive iodine therapy and attend his or her routine 1 week post-radioactive iodine follow-up with routine imaging and collection of the stored contact lenses for measurement of radioactive iodine levels. Patients will also be expected to attend an ophthalmology clinic every 8 months for two years to assess for nasolacrimal duct obstruction.

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Restrictions on daily activities include cessation of any other eye drops outside the designated artificial tear schedule of this study. If you wear biweekly or monthly soft contacts, you must practice early cessation of each contact lens so that the lenses from each day can be collected in a sterile container for analysis. We will reimburse you for each of the contact lenses you dispose of prior the original intended cessation date. For example, if you wear monthly soft contacts on both eyes, we will reimburse you for the cost of 8 monthly soft contacts (4 days worth of bilateral contacts). There are no other costs to you for taking part in this study.

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 are receiving radioactive iodine therapy for thyroid carcinoma and wear bilateral soft contact lenses.

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 will also get this information.

Side effects and risks that you can expect if you take part in this study:

All side effects and risks associated with artificial tears are rare; allergic reaction, including but not limited to skin rash, itching or hives, swelling of the face, lips, or tongue, blurry vision, change in vision, minimal risk to the cornea, watery eyes, eye redness, eye itching, eye irritation, or pain.

Risks that are not known:

None. Preservative-free artificial tears are FDA-approved eye drops used for the treatment of dry eyes and can be obtained over the counter.

Good effects that might result from this study:
The results of the study may provide possible a possible intervention for reducing the risk of developing radioactive iodine associated nasolacrimal duct stenosis.

Procedures to be followed:
You will be instructed to administer artificial tears into the right eye only in the following schedule: Day 1 (day of radioactive iodine therapy): every 15 minutes for 2 hours, then every 30 minutes for at least 4 hours or until bedtime at night
Day 2: once every 1 hour for 12 hours
Day 3: four times
Day 4: two times

You must be wearing bilateral soft contact lenses at the time of radioactive iodine administration and for at least 12 hours a day. Contacts must be worn during artificial tear administration.

Bedtime: remove RIGHT contact first, place in RIGHT lens case. Rinse your hands, pat dry. Then remove left contact, place in LEFT lens case.

Store contacts in different lens case every night before going to sleep. Put a whole vial of GenTeal artificial tears to cover the contact lens in the case. One vial of tears for the right, and one vial of tears for the left.

Day of Imaging (about 1 week after radioactive iodine): **Bring the FOUR lens cases to the appointment so we can collect your contacts**

Ophthalmology Appointments:
1st appointment: prior to radioactive iodine therapy
2nd appointment: 8 months after therapy to assess for nasolacrimal duct obstruction
3rd appointment: 16 months after therapy to assess for nasolacrimal duct obstruction
4th appointment: 24 months after therapy to assess for nasolacrimal duct obstruction

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Payments for your time spent taking part in this study or expenses:
One time $50 gift-card, given at the Nuclear Medicine follow-up appointment about 7 days from radioactive iodine therapy.
Financial reimbursement to replace contact lenses if patient does not wear daily soft contact lenses
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 that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt 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 [redacted] during working hours or my Faculty Attending Ophthalmologist [redacted] during working hours. If you cannot reach the research staff, please page the ophthalmology department at [redacted]

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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 Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
Your study doctor may take you out of this study if staying in the study would be harmful to you or if you fail to follow instructions.

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

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:
Data will be de-identified without any personal information that could connect you to the data. All data and contact lens specimens will be stored in a secure location, which only the study personnel will have access to.

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 or future research. Disclosures that you make yourself are also not protected.

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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.

Study Results:
Results of the study will be shared with the participants of the trial by telephone or during a clinic visit.

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 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.

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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.

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.

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.

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

Consent obtained by:

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_____ _____
Date Signature

_____
Printed Name and Title

Time: _____