Participant ID#: _____

Louisiana State University Health Sciences Center - New Orleans

Consent to Participate in Research

STUDY TITLE: Does Administration of Proparacaine Hydrochloride 0.5% Ophthalmic Solution Prior to Canalicular Probing and Irrigation Decrease Patient Discomfort?

PRINCIPAL INVESTIGATOR: Austin Pharo, M.D

1. Invitation to be Part of a Research Study

Austin Pharo, M.D, and associates from the Ophthalmology Department at the Louisiana State University Health Sciences Center in New Orleans (LSUHSC-NO) are conducting a research study. A research study is a scientific way to improve or develop new methods of health care. Studies are designed to answer specific questions on how to prevent, diagnose, or treat diseases and disorders. The research team is asking you to be in this study to answer the question if Proparacaine (numbing drops) provide a more comfortable experience for you during probing and irrigation of the tear drainage system. **Research studies are voluntary and include only people who choose to take part.** The researchers will explain this study to you and this consent form will help you decide if you want to participate. Before deciding:

- You can discuss this study with friends and family.
- You can also discuss it with your health care doctor or request a second opinion.
- If you have any questions, you can ask the researchers for more information before deciding to participate.
- Even if you choose to participate, you can decide to stop participating at any time.

In this consent form, "you" always refers to the participant. If you are a legally authorized representative, please remember that "you" refers to the study participant.

2. Important Information about this Research Study

This section lists the key characteristics of this study and the basic reasons why you may or may not want to take part. It is only a summary. The sections following this summary have more details, including contact information for people who can answer any questions or concerns you may have. Please take time to read this whole document and ask questions before deciding if you want to take part in this research study.

Things you should know:

- The purpose of the study is to determine if placing a drop of Proparacaine hydrochloride 0.5% (numbing medication) into your eye before probing and irrigation of the tear drainage system will improve your comfort during the procedure.
- In order to participate, you must be 18 and older, you must have signs and symptoms of excess tearing which would require a probing and irrigation procedure of the tear drainage system at LSU Healthcare Network, UMCNO, University Medical Center Lafayette, Our Lady of the Angels, or Eyelid & Facial Consultants.
- If you choose to participate, you will be given 1 drop of Proparacaine (numbing medications) in one eye and a drop of salt solution in the other eye. You will be asked after the procedure which eye was more comfortable during the procedure. Your part in the study will include only the time before, during, and after the procedure.
- The main risks of being in the study are possible reactions to numbing medication (Proparacaine) including stinging, burning and redness of the eye may occur. A rare, allergic reaction of the cornea, inflammation of the iris has been reported. Allergic skin reaction from proparacaine (numbing medication) with drying of the fingertips has also been reported.
- You might benefit from being in the study because using a drop of the numbing medication may provide a more comfortable experience during the procedure.
- Taking part in this research study is voluntary; you do not have to participate. If you do take part, you can stop at any time.

3. Why is this study being done?

It is common for male and female adults of all races with excess tearing to have discomfort during the probing and irrigation of the tear drainage system. Probing and irrigation of the tear drainage system is completed with a thin metal probe that is inserted into an opening in the lower eyelid and extended through the tear drainage system to the opening in your nose. Irrigation of the tear drainage system is then done using a metal syringe, without the needle tip, attached to a syringe to inject a salt solution. This is done to determine if the tear drainage system is open or blocked. The use of a numbing medication during probing and irrigation of the tear drainage system is used in kids but has not been researched in adults. The goal of this study is to determine whether or not placing a drop of Proparacaine hydrochloride 0.5% (numbing medication) into your eye before the probing and irrigation procedure of the tear drainage system will make the procedure more comfortable for you.

Proparacaine hydrochloride is a commonly used numbing medication for minor procedures and is FDA approved for use in eyes.

4. What will happen if I take part in this study?

If you present to ophthalmology clinic at the LSU Healthcare network, UMCNO, University Medical Center Lafayette, Our Lady of the Angels, or Eyelid & Facial Consultants with symptoms of excess tearing, requiring probing and irrigation of the tear drainage system to determine the cause of the excess tearing, you can participate in this study. The consent process to be including in the study will be completed by Dr. Pharo.
Two syringes without needles will hold either Proparacaine solution (numbing medications) or a salt solution (without numbing medication). 1-2 drops of either mixture will be placed into your right or left eye before the probing and irrigation procedure. The order of the syringes will be random and Dr. Pharo will not know which eye gets which solution. Dr. Pharo will be performing the probing and irrigation procedure. If Dr. Pharo notices blockages in the tear drainage system during procedure, you will be excluded from the study.
After completion of the procedure, Dr. Pharo will ask you one question. The question is as follows: "Which side was more uncomfortable during probing and irrigation: right or left?" Your data (age and sex), medication list, and your response to the survey question will be recorded on the LSU research SharePoint site.

Before you begin the study

Before you begin the study, Dr. Pharo will determine if you meet the conditions to be included in the study and have excess tearing during his examination.

During the study

If you agree to take part in this study, you will be asked to undergo the irrigation and probing procedure to be completed by Dr. Pharo. You will receive one drop of the proparacaine (numbing medication) in one eye and one drop of a salt solution in the other eye. You or Dr. Pharo will not know which eye will get the numbing drop and after the procedure is completed Dr. Pharo will verbally ask you which eye was more comfortable.

5. How many people will take part in this study and how long will it last?

145 people will take part in this study at LSUHSC-NO. In total, approximately 145 people will participate in this study

If you complete the entire study, your participation will last for the day of the procedure only.

6. What are the risks of taking part in this study?

Known risks and discomforts

- Occasional temporary stinging, burning and conjunctival redness may occur with the use of proparacaine.
- A rare, severe, immediate-type, apparently hyperallergic corneal reaction characterized by acute, intense and diffuse epithelial keratitis, a gray, ground glass appearance, sloughing of large areas of necrotic epithelium, corneal filaments and, sometimes, iritis with descemetitis has been reported.
- Allergic contact dermatitis from proparacaine with drying and fissuring of the fingertips has also been reported.

7. Are there any benefits to participating in this study?

Possible benefits to you

You might benefit from being in the study because using a drop of the numbing medication may provide a more comfortable experience during the procedure. There will be no financial compensation for participating in this study.

Possible benefits to others or society

This study will help the researchers learn more about whether numbing medication will make probing and irrigation procedure more comfortable for patients versus not using numbing medication. This information may help in the treatment of future patients with excess tearing.

8. What other choices do I have if I don't take part in this study?

You do not have to take part in this research study. Other options for you include completing the irrigation and probing procedure without topical anesthetic (numbing medication).

9. How will my information be kept confidential?

The researchers will protect your information by storing patient health information in a secured server on LSU Healthcare Network Sharepoint. We will make every effort to maintain your privacy but we cannot guarantee complete confidentiality. For example, there is always a risk of someone breaking into a computer system where your information may be stored. Federal or state law also may require us to disclose your records. Loss of confidentiality is a potential risk of taking part in this study.

The following people or groups may review your study records for purposes such as quality control or safety:

- Representatives of LSUHSC-NO and the LSUHSC-NO Institutional Review Board
- Other organizations or agencies if required by law.

10. Will my information or specimens be used for future research?

We will not use or share any of your information and as part of this study for future research, even if identifiers are removed. Any samples obtained for this study will be discarded or destroyed once they have been used for their intended purpose(s) in this study.

11. Will there be any costs to me for taking part in this study?

If you take part in this study, you will not have any expenses beyond the routine costs for patients with similar conditions.

We will bill you and/or your insurance company (or healthcare plan) for the costs of any standard medical care you receive during your participation in the study. This includes standard medical care to treat any known or unknown side affects you may experience. There is a possibility that your insurance company may not cover these costs because you are in a research study. If this happens you might have unexpected expenses. If the insurance company does pay for the standard care, you may be responsible for any copayments and deductibles.

We do not have money to pay for any disability, damages such as lost wages, or similar outcomes that you may experience.

12. Will I be paid or for taking part in this study?

You will not receive any type of payment for taking part in this study.

13. Who can profit from study results?

Not Applicable

14. What should I do if I get sick or injured during the study?

If you believe the research procedures have made you sick or caused an injury to you, immediately seek medical advice and/or treatment by:

- Contacting the Principal Investigator and/or the Co-Investigator whose phone numbers are listed in the next section; and/or

- Calling the Research Injury phone number listed in the next section; and/or • Contacting your regular medical doctor; and/or
- Contacting the treatment center of your choice.

In the event of study-related harm, you will be responsible to call the above provided phone numbers to describe the nature of your injury and to arrange medical care to further investigate injury. Your insurance company will be responsible for paying for the care provided to treat injuries if present.

If the insurance company does pay for the care and treatment of study-related injury, you may be responsible for any co-payments and deductibles.

15. Who can I contact if I have questions about this study?

The research team:

You may contact the following individuals with any questions or concerns about the research or your participation in this study.

Principal Investigator

Name: Austin Pharo, MD

Address: 3700 St. Charles Ave, New Orleans, LA 70115

Phone #: 504-891-1116

Co-Investigator

Name: Jonathan S. Williams, MD PGY-III

24 Hour Injury Phone Number:

Phone #: 504-412-1200

Office of the Chancellor, LSU Health Sciences Center - New Orleans:

You may contact the Office of the Chancellor by phone at (504) 568-4801, if

- you have questions about your rights while taking part in this study, or
- you have any concerns or suggestions, and
- want to talk to someone other than the researchers about the study.

Public information about this study:

ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available at 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.

The National Clinical Trials number for this study is NCT 04229771.

16. What will happen if I cannot complete the study?

There are several reasons why you may not complete the study.

The researchers or the study sponsor might decide to stop the study at any time.

The researchers may end your participation in this study, without your permission, for a number of reasons including:

- Your safety and welfare are at risk.
- You do not follow instructions.
- You miss scheduled visits.
- You fail to complete study activities.

You also may decide on your own to stop participating in the study. If you are thinking about withdrawing, let the researcher know so he/she may remove you from the study safely. You also should seek medical advice for alternative treatments. The researcher will inform you of any new findings during the study that may impact your decision to continue participation.

If you decide to stop being in the study, or the study is stopped, or you are removed from the study, the researcher will ask you to complete an exit interview.

You are not required to complete these tasks but some of them may be for your own safety.

Information collected about you up to the point of withdrawal will remain part of the study. You may not remove this data from the study database. We will keep this information confidential.

17. Your Participation in this Study is Voluntary

Taking part in this study is your choice. You are free not to take part or to withdraw at any time for any reason or no reason at all. No matter what you decide, there will be no penalty to you and you will not lose any services, benefits or rights you would normally have.

If you are a LSUHSC-NO student or faculty/staff member, you may choose not to be in the study or to stop being in the study before it is over at any time. Your decision will not affect your grades or job status at LSUHSC-NO. You will not be offered or receive any special consideration if you take part in this research study.

18. Your Consent

By signing this document, I acknowledge or am aware that:

- The researcher(s) discussed the study with me and answered all my questions.
- I will receive a copy of the consent form.
- I do not waive any of my legal rights by signing this consent document.
- I can contact the study team or the Chancellor's Office using the contact information provided above if I have any questions or concerns after signing the consent form.

Participant ID#: _____

Signature of Participant:

I agree to take part in this study.

_____

Participant Signature | Printed Name | Date

Signature of Reader & Witness to Consent of Subjects Who Cannot Read:

The study subject has indicated to me that he/she is unable to read. I represent that the consent form was presented orally to the subject in the subject's own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her consent for participation by completing the signature line above.

_____

Reader Signature | Printed Name | Date

_____

Witness Signature | Printed Name | Date

Participant ID#: _____

Signature of Legally Authorized Representative for Adult:

I am a legally authorized representative of the person named below. I agree for this person to take part in this study.

_____

Name of Participant (Please print)

Type of LAR (Check applicable box):

- ☐ Court-appointed Guardian
- ☐ Health Care Proxy
- ☐ Durable Power of Attorney
- ☐ Family Member/Next-of-Kin. Relationship: _____
- ☐ Other: _____

_____

LAR Signature Printed Name Date

Signature of Person Obtaining Consent:

I have explained the research to the subject and answered all his/her questions. I will give a copy of the signed consent form to the subject.

_____

Signature of Person Obtaining Consent Printed Name Date