UNIVERSITY OF CALIFORNIA, SAN FRANCISCO & SAN FRANCISCO VA
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Bacteriostatic Saline as a Local Anesthetic in Minor Eyelid Procedures

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This is a clinical research study about pain during local anesthesia for minor procedures of the eyelids and around the eye. We aim to see if bacteriostatic saline, which is already commonly used in the medical field, is less painful to inject but provides the same level of anesthesia during the procedure. At least one of the study researchers in the department of Opthalmology, Robert Kersten, MD; Reza Vagefi, MD; Bryan Winn, MD; Seanna Grob, MD; Meleha Ahmad, MD; or their associates, will explain this study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you are welcome to ask the researchers.

You are being asked to take part in this study because you have the condition listed above and could help us learn more about how to reduce pain during minor eyelid procedures in future patients like you.

Why is this study being done?

The purpose of this study is to try to reduce pain incurred during office-based procedures on and around the eyelids.

This study is not funded. The investigators do not have any financial interests to disclose.

How many people will take part in this study?

About 150 people will take part in this study. Participants will be recruited from UCSF and will include patients undergoing an in-office procedure at UCSF Oculoplastics clinic.

What will happen if I take part in this research study?

If you agree, the following procedures will occur:

- You will be “randomized” to receive one of two local anesthetic agents prior to your office-based eyelid procedure. Both agents are federal drug agency (FDA)-approved, however one agent is the “standard of care” (what is most often used), whereas the other agent is experimental. The experimental agent has been utilized in other parts of the body for many years and has been used around the eye in combination with other medications. But, it has

not been used on its own for local anesthesia around the eye. Randomization means that you are put into a group by chance. A computer program will place you in one of the groups. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in any group.
- You will undergo your eyelid procedure in the same fashion as if you had not participated in the study
- You will be asked about pain level on a 0 to 10 scale during anesthetic injection and during your eyelid procedure

Study location: These procedures will be done at UCSF's Oculoplastics clinic

How long will I be in the study?

Participation in the study will add an additional 5-10 minutes to your study visit. You will need to answer questions regarding your pain level during anesthetic injection and procedure itself. No additional visits will be required by your participation in this study.

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop participating in the study. We will revert to administration the surgeons standard-of-care local anesthetic at your request.

Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

- You may have side effects while in the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or serious, including local allergic reaction, fast heart rate or pain. Your health care team may give you medicines to help lessen the side effects.
- You will be assigned to an anesthetic type by chance, and the treatment you receive may prove to be less effective or to have more side effects than the other study treatment or other available treatments.
- You may experience allergic reaction, more or less pain or bleeding with local anesthetic or during the procedure depending on which local anesthetic you are randomized to.
- For more information about risks and side effects, ask one of the researchers.

Are there benefits to taking part in the study?

There will be no direct benefit to you from participating in this study and benefits cannot be guaranteed. However, the information that you provide may help health professionals better understand/learn more about what local anesthetics are most comfortable for patients undergoing eyelid procedures like yours.

What other choices do I have if I do not take part in this study?

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will still undergo your eyelid procedure as planned, and you can still get your care from our institution the way you usually do.

Will information about me be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. If you do not have a UCSF medical record, one will be created for you. Your signed consent form and some of your research tests will be added to your UCSF medical record. Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records and may be added to your medical record. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Are there any costs to me for taking part in this study?

Two types of procedures will be done during this study. Some are part of your standard medical care and others are only for research. You or your insurer will be billed for the standard medical care. You will be responsible for your co-pays, deductibles, and any other charges that your insurer will not pay. There is a possibility that your insurer may not cover all standard medical care costs if you are receiving medical services out of network. Any procedures done only for research will not be charged to you or your insurer.

If you have questions about what costs you will be responsible for, please talk with the study investigator before deciding to enroll in the study. Depending on the type of study, some of your costs could be substantial.

Will I be paid for taking part in this study?

You will not be paid for taking part in this study.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, Dr. Robert Kersten, if you feel that you have been injured because of taking part in the study. You can tell the doctor in person or call him at 415-353-2800.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

Who can answer my questions about the study?

You can talk to the researcher(s) about any questions, concerns, or complaints you have about this study. Contact the researcher(s) Meleha Ahmad, MD and Robert Kersten, MD at 415-353-2142.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at 415-476-1814.

CONSENT

You have been given a copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date	Participant's Signature for Consent
Date	Person Obtaining Consent