Official Title: A Prospective Randomized Clinical Trial Comparing Three Delivery Methods of Mitomycin-C for Trabeculectomy Surgery: Preoperative Subconjunctival Injection, Intraoperative Subconjunctival Injection, and Topical Application (Conventional Use) During Trabeculectomy Surgery

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UNIVERSITY OF CALIFORNIA LOS ANGELES
CONSENT TO PARTICIPATE IN RESEARCH

A Prospective Randomized Clinical Trial Comparing Three Delivery Methods of Mitomycin-C for Trabeculectomy Surgery: Preoperative Subconjunctival Injection, Intraoperative Subconjunctival Injection, and Topical Application (Conventional Use) During Trabeculectomy Surgery

Comparing Preoperative Injection of Mitomycin-C vs. Intraoperative Injection of Mitomycin C. vs. Topical Application of Mitomycin-C (Conventional Use) in Trabeculectomy

INTRODUCTION

Joseph Caprioli MD and associates from the Glaucoma Division, Jules Stein Eye Institute at the University of California, Los Angeles are conducting a research study.

The researchers will explain this study to you. **Research studies are voluntary and include only people who choose to take part.** Please take your time about deciding whether to participate in this study. 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.

The research team is asking you to be in this study because you have been diagnosed with primary open angle glaucoma and require glaucoma surgery to lower your intraocular pressure.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to evaluate the effects of injection of an antimetabolite (Mitomycin C) two to four weeks before the glaucoma surgery (Trabeculectomy) or injection during the surgery and its outcome. Mitomycin C (MMC) is an antimetabolite commonly used at the time of glaucoma surgery, either by using a soaked sponge in the 0.02 mg/mL solution or injecting the same solution underneath the conjunctiva, which is the most superficial part of the eye. MMC will decrease the number of fibroblasts, which are the cells responsible for scarring, a common cause of failure of the surgery.

The following definitions may help you understand how this research study is designed: Patients who are eligible for the study will be randomly divided (like a flip of a coin) into three groups. In all groups, eyes will be numbed with topical anesthetic drops for at least 2 minutes before any injection, to allow the eye to be numbed and decrease eye discomfort. Group A will receive a 0.1ml injection of MMC 0.002% (which is ten times more diluted than the concentration usually used at the time of surgery) beneath the

conjunctiva, ***two to four weeks*** before the surgery. To avoid any loss of MMC from the surface, a cotton-tip applicator will be used to put pressure on the injection site. Thirty seconds after the injection, the eye will be washed with at least 30 milliliters of balanced salt saline. Group B will receive a 0.1 mL injection of MMC 0.01% to the trabeculectomy site during surgery day. Group C will receive topical administration of MMC during surgery day by applying a sponge soaked in 1 mL of 0.02 mg/mL for one minute to the site of trabeculectomy surgery. Please note that all three groups will receive MMC, but the only difference is the different times and delivery method at which they are applied. Group A will receive MMC two to four weeks before the surgery while Group B and C will receive the MMC at the time of surgery.

All groups will have routine preoperative preparation, then undergo routine conventional trabeculectomy, and will receive the routine postoperative medication and care.

This study is being funded by the Glaucoma Division.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

150 people will take part in this study at UCLA.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

Before you begin the study:
Before you begin the study, you will need to be seen by your Glaucoma specialist, who will determine your eligibility to be included in this study during a routine scheduled visit. No additional tests, visits, or imaging is needed.

During the study:
If you take part in this study, you will be randomly placed into one of three groups. Group A will receive a 0.1mL injection of MMC 0.002% (which is ten times more diluted than the concentration usually used at the time of surgery) beneath the conjunctiva, two to four weeks before the surgery. Thirty seconds after the injection, the eye will be washed with large amounts of sterile saline solution. After this procedure, you will continue your routine before surgery with the standard medication and preparation. You will receive a phone call from one of the research team members one week after your injection to assess any side effects of the procedure. If any are reported, a follow-up may be scheduled in the clinic. Group B will receive a 0.1 mL injection of MMC 0.01% to the trabeculectomy site during surgery day. Group C will receive topical administration of MMC during surgery day by applying a sponge soaked in 1 mL of 0.02 mg/mL for one minute to the site of trabeculectomy surgery. The type of surgery planned for you is the same as any other glaucoma surgery of the same kind (Trabeculectomy). You will also receive the routine postoperative medication and care. Routine follow up visits after the surgery will be planned for you.

Routine visits after the surgery are planned for all three groups and data from these standard of care visits will be collected for the study for one year after your operation. Data will be collected from your pre-operative visit and from your standard of care visits that are done at one day, one week, one month, three months, six months, and one year after your operation.

HOW LONG WILL I BE IN THIS STUDY?

This study will last one year after the date of the surgery and all visits are part of standard of care.

WHAT KINDS OF RISKS OR DISCOMFORTS COULD I EXPECT?

Known risks and discomforts:
The possible risks and/or discomforts associated with the procedures described in this consent form include: (these side effects are based on previous studies)

- Scleral whitening
- Scleral hypo vascularity (lack of blood vessels in the underlying wall of the eye)
- Scleral melting
- Endophthalmitis (inflammation of the interior of the eye caused by infection)
- Hyperemia (excess of blood in vessels to the eye)
- Corneal damage
- Cataract (clouding of the eye)
- Scleral thinning or ulceration
- Hypotony (low pressure in the eye)
- Late infection (years after MMC administration) in the eye

The risks and/or discomforts listed above are the same for all study arms but might be higher with the group that receives the MMC injection one month before the surgery. The possible risks and/or discomforts listed above can result in loss of vision and the need for an additional surgery.

Unknown risks and discomforts:
The experimental treatments may have side effects that no one knows about yet. The MMC injection before surgery might have more adverse effects or be less effective than the standard of care procedure. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

ARE THERE ANY BENEFITS IF I PARTICIPATE?

Possible benefits to me:
The possible benefits you may experience from being in this study include a better outcome from the glaucoma surgery and less scarring (which usually causes failure of the surgery).

Possible benefits to others or society:
There will be no direct benefit to you from participating in this study. This study will help the researchers learn more about Trabeculectomy and MMC usage in this surgery. We hope that this information will help in the treatment of future patients with Glaucoma like yours.

WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?

If you decide not to take part in this study, or if you withdraw from this study before it is completed, the following alternative procedures or courses of treatment are available: Routine care and surgeries will be available for you, and you will not be withheld from any type of treatment due to your withdrawal from study. If you choose not to participate, you will continue with routine care.

CAN THE RESEARCHERS REMOVE ME FROM THIS STUDY?

The researchers may end your participation in this study for a number of reasons, such as if your safety and welfare are at risk, if you do not follow instructions or if you miss scheduled visits. The researchers or the study sponsor might also decide to stop the study at any time.

If you decide to stop being in the study, or are removed from the study, or the study is stopped the researcher will ask you to return for a final close-out visit and then routine follow up will be scheduled for you.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?

The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security. Data will be used for future research.

Use of personal information that can identify you:
All identifiers will be deleted from stored information and each patient will be given a unique number (patient ID) which is only used for the study and will not be linked to any identifying data.

How information about you will be stored:
All the information will be stored in an encrypted Excel sheet that only research team members have access to.

People and agencies that will have access to your information:
Only the research team will have access to stored information, and these stored information, as mentioned above, does not have any identifying data.

The research team, authorized UCLA personnel and regulatory agencies such as the Food and Drug Administration (FDA), may have access to study data and records to monitor the study. Research records provided to authorized, non-UCLA personnel will not contain identifiable information about you. Publications and/or presentations that result from this study will not identify you by name.

How long information from the study will be kept:
Information will be held in the database for 3 years after completion of the study.

ARE THERE ANY COSTS FOR TAKING PART IN THIS STUDY?

The study will pay for research-related items and/or services that are provided only because you are participating in the study. These research-related items and/or services are explained in other areas of this consent form.

You or your health plan may be responsible to pay for all the types of items listed below:

- Items and services that would have been provided to you even if you were not in the study
- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items and/or services.

WILL I BE PAID FOR MY PARTICIPATION?

You will not be paid for your participation in this research study.

WHAT OTHER THINGS SHOULD I CONSIDER BEFORE PARTICIPATION?

Researcher Financial Interests in this Study

There are no financial interests in this study.

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

The Research Team:
You may contact Dr. Joseph Caprioli at 310-794-9442 with any questions or concerns about the research or your participation in this study. You can also call the UCLA Page Operator at (310) 825-6301 to reach Dr. Joseph Caprioli 24 hours a day, 7 days a week.

UCLA Office of the Human Research Protection Program (OHRPP):
If you have questions about your rights while taking part in this study, or you have concerns or suggestions and you want to talk to someone other than the researchers about the study, you may contact the UCLA OHRPP by phone: (310) 825-5344; by email: mirb@research.ucla.edu or U.S. mail: UCLA OHRPP, 11000 Kinross Ave., Suite 211, Box 951694, Los Angeles, CA 90095-1694.

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 on 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.

WHAT HAPPENS IF I BELIEVE I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number(s) listed above.

If you are injured as a result of being in this study, UCLA will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or the study, or billed to you or your insurer just like other medical costs, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about this, you may call the UCLA Office of the Human Research Protection Program at 310-825-5344 or send an email to mirb@research.ucla.edu.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

Taking part in this study is your choice. You can choose whether or not you want to participate. Whatever decision you make, there will be no penalty to you and you will not lose any of your regular benefits.

- You have a right to have all of your questions answered before deciding whether to take part.
- Your decision will not affect the medical care you receive from UCLA.
- If you decide to take part, you can leave the study at anytime.

- If you decide to stop being in this study you should notify the research team right away. The researchers may ask you to complete some procedures in order to protect your safety.
- If you decide not to take part, you can still get medical care from UCLA.

HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

If you agree to participate in this study you should sign and date below. You have been given a copy of this consent form and the Research Participant'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.

SIGNATURE OF THE PARTICIPANT

_____
Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF PERSON OBTAINING CONSENT

_____ _____
Name of Person Obtaining Consent Contact Number

_____ _____
Signature of Person Obtaining Consent Date