APPROVED BY SALUS IRB: 09 AUGUST 2019

AN AGREEMENT TO BE IN A RESEARCH STUDY
INFORMED CONSENT DOCUMENT

Sponsor: SR Cornea Consultants
City and State: Oak Brook, IL

Protocol Number and Title: 10; Evaluation of Intraoperative use of Dexycu on the Signs and Symptoms of Dry Eye

Study Doctor: Sanjay N. Rao, MD

Address of Study Site(s): Hauser Ross Surgical Center
1630 Gateway Drive
Sycamore, IL 60178

24-Hour Telephone Number: 800-243-2587

INTRODUCTION

You are being invited to take part in a medical research study. Before you decide to take part in this study, you should read this document. This document, called an informed consent document, explains the study. Please ask as many questions as needed so that you can decide if you want to be in the study.

To be in this research study, you cannot already be in another medical research study.

You must be honest and complete in providing your medical history. Giving false, incomplete, or misleading information about your medical history, including past and present drug use, could have very serious health consequences.

PURPOSE OF THE STUDY

This study is being done to see if the addition of a United States Food and Drug Administration (FDA) approved intraoperative injection of steroid improves the signs and symptoms of dry eye after cataract surgery. The study medication is called Dexycu. Dexycu is approved by the FDA and is indicated for the treatment of inflammation after eye surgery.

WHAT WILL HAPPEN DURING THE STUDY

You will have medical tests done to help the study doctor decide if you can be in the study. This is called "screening."

Screening does not guarantee entry into the study. Entry into the study will depend upon the results of your dry eye tests, study specific guidelines, and the decision of the study doctor. Even if you pass the screening tests, there is a chance that you will not be invited to take part in the study. There may be other reasons why you cannot take part in the study. The study doctor and/or the study staff will discuss these with you.

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About 40 males and females, ages 18 and older, who are having cataract surgery will take part in the study. The study will take place at Hauser Ross Eye Institute and you will be in study for 21 days.

PROCEDURE:
If you are enrolled in the study, there is a 1 in 2 chance of receiving the study medication, Dexycu, during cataract surgery. Whether you receive the intraoperative injection will be decided by chance (like the flip of a coin).

If you qualify for the study, you will be asked to attend your standard postoperative visits in the study clinic at Day 1, Day 7, and Day 21. On Day 7 and Day 21, you will have additional dry eye testing. It is very important that you are able to keep these appointments as they are scheduled.

While you are in the study, you can use some medicines, such as tear substitutes, steroid and antibiotic eyedrops (the standard drops after cataract surgery), as well as medications you were taking prior to the study. If you become sick during the study for any reason, be sure to contact the study staff and explain what happened (even if you go to another doctor).

The eye tests done during this study are not new or experimental.

Screening Visit:
At the screening visit, you will have a comprehensive cataract evaluation, including dry eye testing. If it is determined that you have cataracts in both eyes, and you wish to proceed with surgery, you will be given the opportunity to participate in the study.

Day of cataract surgery:
Dexycu will be administered as a single intraocular injection if you are assigned to receive the injection.

Visit 1:
This visit is one day after your cataract surgery. At the one day postoperative visit, you will be asked about the symptoms in your operated eye, have tests to measure your vision, have eye pressure measurements and eye dilation. The eye tests done during this visit are not new or experimental. The study staff will also review your postoperative medication regimen which will include anti-inflammatory eyedrops and antibiotic eyedrops.

Visit 2:
The second visit will be about 7 days after your surgery. You will be asked again about the symptoms in your operated eye, any changes in medication you have taken and your general health. The study doctor will do some of the same tests that he did at the first visit (put drops in your eyes, look at your eyes, test for how

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well you can see, and check the pressure inside your eyes). In addition, you will have dry eye test called tear film osmolarity and corneal staining.

Visit 3:
The third visit will be about 21 days after your surgery. You will be asked again about the symptoms in your operated eye, any changes in medication you have taken and your general health. The study doctor will do some of the same tests that they did at the first visit (put drops in your eyes, look at your eyes, test for how well you can see, and check the pressure inside your eyes). In addition, you will have dry eye tests called tear film osmolarity and corneal staining.

SIDE EFFECTS AND OTHER RISKS
Below is a list of the most common side effects of the study drug, Dexycu:

Dexycu contains dexamethasone. Dexamethasone is in a class of drugs called corticosteroids. Corticosteroids are used to treat inflammation (swelling). The most common side effects are increases in eye pressure, temporary swelling in the cornea, and inflammation in the eye. Other side effects of steroids may include:

- Suppression of the immune system (decreased ability to fight infection)
- Delayed healing
- Increased Pressure in the eye
- Secondary eye infections
- Increased blood sugar levels
- Swelling in the cornea
- Swelling on the inside of the eye
- Corneal endothelial cell loss (some cells in the eye can be lost)
- Blurred vision
- Photophobia (sensitivity to light)
- Vitreous detachment

UNFORESEEABLE RISKS
All drugs can have side effects or affect another drug that you are taking. Therefore, the use of this study drug may involve risks to you that are presently unforeseen and unknown.

Also, any drug may trigger a serious allergic or other reaction and may cause the following:

- rash,
- hives,
- itching,
- tingling and swelling of the face, lips, tongue, throat and/or vocal cords,
- difficulty breathing,
- wheezing,
- very low blood pressure,
- seizures (convulsions),

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- loss of consciousness, and
- possibly death.

Drugs may cause temporary changes in blood chemistries and other blood tests.

You must tell the study doctor or study staff about all side effects that you have. If you are not honest about your side effects, it may not be safe for you to stay in the study.

POSSIBLE BENEFITS OF THE STUDY
The benefit of participating in this study may or may not be an improvement in signs and symptoms of dry eye after cataract surgery. Many people who have cataract surgery experience dry eyes after surgery. By participating in this study, we can better understand if an intraoperative injection of Dexycu can benefit the health of the eye and improve dry eye after surgery.

PAYMENT FOR BEING IN THE STUDY
You will not be paid for being in this study.

The Study Doctor is a consultant to the sponsor of the research and has financial ties to the research. As a researcher in this study, he/she is interested not only in your health and well-being, but also in the results of this study. It is possible that sometimes these two goals may conflict with one another. Researchers protect the rights and interests of participants by carefully following the rules of the study.

ADDITIONAL COSTS
You do not have to pay for study visits, dry eye tests, injection of Dexycu and postoperative visits that are done for the study. You or your insurance company may have to pay for routine care you would receive whether or not you are in the study. Your insurance company may or may not pay for procedures that are a part of a research study. You should contact your insurance company for more information.

ALTERNATIVES TO PARTICIPATION
There are other treatments available for dry eye after cataract surgery if you decide not to be in the study. These treatments include:

- artificial tear substitutes
- punctal occlusion
- anti-inflammatory eyedrops

You and your personal doctor can decide what treatment is best for you.

RELEASE OF MEDICAL RECORDS AND PRIVACY
Your study records will be kept private. There may be times when the study doctor will not be able to guarantee privacy, such as when your study medical records are

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requested by a court of law or when shared with a firm in another country that does not have privacy regulations in place. Salus IRB and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, your total privacy cannot be guaranteed. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The following people will have access to your study records:

- Sanjay N. Rao, MD, study doctor
- Study Monitor or Auditor
- SR Cornea Consultants
- Salus IRB

Salus IRB has approved this study and this informed consent document. Salus IRB is a committee of scientific and non-scientific individuals who review, require modifications to, and approve or disapprove research studies by following the federal laws. This group is also required by the federal regulations to provide periodic review of ongoing research studies.

IN CASE OF AN INJURY RELATED TO THIS RESEARCH STUDY

It is important that you tell your study doctor, if you feel that you have been injured because of taking part in this study. You can tell the study doctor in person or call them at the number listed on the first page of this consent document. Any study and non-study related injuries will be paid by the principal investigator. Medical treatment will be provided at no cost to you or your insurance company for a research-related injury.

LEGAL RIGHTS

You do not lose any legal rights by signing this consent document. The above statement, "In Case of an Injury Related to This Research Study," does not stop you from seeking legal help in case of negligence.

NEW FINDINGS

During the study, you will be told of any important new findings about the study. You can then decide if you still want to be in the study.

WHOM TO CONTACT

You may contact the study doctor or study staff at the phone number listed on the first page of this consent document:

- for answers to questions, concerns, or complaints about this research study,
- to report a research related injury, or
- for information about study procedures.

If you need medical attention please go to the nearest emergency room.

You may contact Salus IRB if you:

- would like to speak with someone unrelated to the research,

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- have questions, concerns, or complaints regarding the research study, or
- have questions about your rights as a research participant.

Salus IRB
2111 West Braker Lane, Suite 100
Austin, TX 78758
Phone: 855-300-0815 between 8:00 AM and 5:00 PM Central Time
Email: salus@salusirb.com

If you would like additional information about your rights, research in general, or IRBs, you may visit www.salusirb.com.

LEAVING THE STUDY

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. You have the right to leave this study at any time. If you do not want to be in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

If you wish to leave this study, please call the study doctor or study staff at the telephone number listed on the first page of this consent document to schedule study exit procedures.

You are being invited to take part in this study because you are having cataract surgery. If you withdraw from the study you should contact your personal doctor to seek alternative treatment options.

Your part in this study may be stopped at any time without your permission. The following people can stop your participation and/or the study itself:

- Study Doctor
- Sponsor Company
- Salus IRB

If you do not follow the study procedures you may be taken out of the study.

If you withdraw from the study, no new data about you will be collected for study purposes. All data that have already been collected for study purposes will be shared with the study sponsor.

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AGREEMENT TO BE IN THE STUDY

This consent document contains important information to help you decide if you want to be in this study. If you have any questions that are not answered in this consent document, please ask the person explaining this document or one of the study staff.

By consenting to participate you agree that you have been given a copy of all pages of this consent document. You have had an opportunity to ask questions and received satisfactory answers to all your questions about this study. You understand that you are free to leave the study at any time without having to give a reason and without affecting your medical care. You understand that your study-related medical records may be reviewed by the company sponsoring the study and by government authorities.

**IF YOU DO NOT AGREE WITH THE STATEMENT ABOVE,
YOU SHOULD NOT SIGN THIS INFORMED CONSENT DOCUMENT.**

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Printed Name of Person Explaining Informed Consent Document

_____ _____
Signature of Person Explaining Informed Consent Document Date

You will be given a signed and dated copy of this informed consent document to keep.

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