IRB APPROVED
Aug 12, 2025

RESEARCH SUBJECT CONSENT FORM
The LaReCa Study

TITLE: A Prospective, Single-Arm Study Evaluating Crosslinked Hyaluronate Canalicular Gel for the Treatment of Dry Eye Disease in Patients Undergoing Refractive Cataract Surgery

PROTOCOL NO.: None
WCG IRB Protocol #20252708

SPONSOR: Vance Thompson Vision, Prof LLC

CO-INVESTIGATORS: Vance Thompson, MD
3101 W 57th St
Sioux Falls, South Dakota 57108
United States of America

Kayla Karpuk, OD
5003 S. Bur Oak Place
Sioux Falls, South Dakota 57108
United States of America

STUDY-RELATED PHONE NUMBER(S): Phone Number: 605-361-3937
Phone Number (24 hours): 1-605-361-3937

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have questions, concerns, or complaints, or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

What should I know about this research?

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

How long will I be in this research?
We expect that your taking part in this research will last up to 6 months

Why is this research being done?
The purpose of this research is to understand how lacrimal occlusion (blocking the tear duct) with Lacrifill Canalicular Gel (crosslinked hyaluronate) prior to cataract surgery improves dry eye findings in patients who undergo refractive cataract surgery.

Lacrifill Canalicular Gel has been cleared by the FDA for the treatment of dry eyes.

What happens to me if I agree to take part in this research?
If you decide to take part in this research study, the general procedures include a review of ocular history, vision checks, a one time administration of crosslinked hyaluronate canalicular gel prior to cataract surgery, dry eye disease questionnaires, objective dry eye disease measurements. measurements of the length of your eye, and eye examinations using a microscope. The cataract surgery that you have elected to proceed with is not part of this study.

Could being in this research hurt me?
The most important risks or discomforts that you may expect from taking part in this research include mild discomfort and tenderness near administration site of crosslinked hyaluronate gel.

Will being in this research benefit me?
Possible benefits to you include temporary improvement in dry eye symptoms and ocular comfort following cataract surgery.

Possible benefits to others include improved signs and symptoms of dry eye during the pre- and post-operative time of cataract surgery.

What other choices do I have besides taking part in this research?
You can be treated with Lacrifill or other approved medications without being in this study.

What else should I know about this research?
Other information that may be important for you to consider so you can decide whether to take part in this research is.

There is a possibility that your deidentified information or biospecimens may be used or distributed for future research studies without your additional informed consent.

DETAILED RESEARCH CONSENT
You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

What should I know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to understand patient reported outcomes and objective assessments of dry eye disease following administration of Lacrifill (crosslinked hyaluronate gel) in patients undergoing cataract surgery with advanced technology intraocular lenses.

About 60 subjects will take part in this research.

How long will I be in this research?

We expect that your taking part in this research will last a total of 4 to 6 months.

What happens to me if I agree to take part in this research?

During this study, the following procedures will be completed. Some may occur more than once during your participation in the study.

Screening Visit:

- Informed consent obtained prior to any data collection
- Review of demographics and ocular history
- Inclusion and exclusion criteria will be reviewed
- You will be asked to respond to standardized questionnaires assessing symptoms associated with dry eye disease
- Vision will be measured both with and without best correction
- Biometry, measurements of the length of your eye, will be taken
- Objective dry eye measurements will be obtained specifically to measure how quickly your natural tears break apart and the height of the tears at the front of your eye.
- Fluorescein dye will be used to assess dry areas on the cornea (front windshield of the eye)
- Administration of Lacrifill (crosslinked hyaluronate gel) will be administered to both eyes

1st and 2nd visits (operative days)

- Biometry, measurements of the length of your eye, will be obtained
- Cataract surgery as planned

1-2 Days after surgery
- Visual acuity measurements
- Intraocular pressure measurements
- Corneal fluorescein staining

5-9 Days after surgery
- Dry eye questionnaires
- Objective dry eye measurements will be obtained specifically to measure how quickly your natural tears break apart and the height of the tears at the front of your eye.
- Uncorrected and best corrected visual acuity
- Corneal fluorescein staining

21-37 Days after surgery
- Dry eye questionnaires
- Objective dry eye measurements will be obtained specifically to measure how quickly your natural tears break apart and the height of the tears at the front of your eye.
- Uncorrected and best corrected visual acuity
- Corneal fluorescein staining
- Dilated eye exam

76-104 Days, or 3 months, after surgery
- Dry eye questionnaires
- Objective dry eye measurements will be obtained specifically to measure how quickly your natural tears break apart and the height of the tears at the front of your eye.
- Uncorrected and best corrected visual acuity
- Corneal fluorescein staining

All study related procedures will be completed in a clinical exam room or pre-testing areas. All subjects will undergo the same study related assessments. The cataract surgery you have elected to undergo is not part of this research study.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:
- Follow the instructions you are given
- Come to the clinic for the study visits at the time you are scheduled
- Tell the study doctor or staff about any changes to vision or ocular irritation
- Tell the study doctor or staff if you want to stop participating in the study at any time.

Could being in this research hurt me?

The risks associated with participation in this clinical research study are expected to be minimal.

These include:
- Temporary blurry vision
- Temporary ocular irritation, stinging, or burning
- Local tenderness at the administration site
- Excessive tearing following administration

There is always the risk that uncommon or unknown side effects may occur. If you have any kind of unusual symptoms, you should report them to your study doctor right away. If you become in any way concerned or would like to have more information, please contact your study doctor.

You are not permitted to participate in this study if you are pregnant, intend to become pregnant or breastfeeding a baby. If you are a female able to bear children you must have a negative urine pregnancy test before participating in the study. Should you become pregnant while participating in this study, please notify your study doctor.

In addition to these risks, taking part in this research may harm you in unknown ways.

Will it cost me money to take part in this research?

There are no additional costs to participate in this clinical research. You may have other costs outside of this study that are associated with cataract surgery and the lens you have chosen at the time of cataract surgery.

In some cases, insurance does not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

Will being in this research benefit me?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to you include temporary improvement in dry eye symptoms and ocular comfort following cataract surgery. You may also experience an improvement in visual quality.

If the study results demonstrate a benefit, then this approach may be more widely used and possible benefits to others will then also include temporary improvement in dry eye signs and symptoms, including improvement in visual quality, following cataract surgery.

What other choices do I have besides taking part in this research?

You can be treated with Lacrifill or other approved medications without being in this study.

What happens to the information collected for this research?

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration (FDA)
- WCG IRB, the Institutional Review Board (IRB) that reviewed this research

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Data or specimens collected in this research might be deidentified and used for future research or distributed to another investigator for future research without your consent.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or clientcare@wcgclinical.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

What if I am injured because of taking part in this research?

If you are injured or get sick because of being in this research, call the study doctor immediately. The study doctor will provide emergency medical treatment. Your insurance may be billed for this treatment. The sponsor will pay any charges that are not covered by insurance or the government, provided the injury was not due to your underlying illness or condition and was not caused by you or some other third party. No other payment is routinely available from the study doctor or sponsor.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- You have a side effect that requires stopping the research
- You need a treatment not allowed in this research
- You become pregnant
- The research is canceled by the FDA or the sponsor
- You are unable to use the research product
- You are unable to keep your scheduled appointments

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?

If you decide to leave this research, contact the research team so that the investigator can properly discontinue your participation. There are no consequences to your withdrawing, your decision will be respected, no prejudice or bias will be shown towards you for your routine medical care. If you decided to take part in this study, but later withdraw for any reason, study data prior to your withdrawal may still be used.

Will I be paid for taking part in this research?

For taking part in this research, you may be paid up to a total of $595. Your compensation will paid incrementally at the completion of each visit as follows:
Visit 1 - $100
Visit 2 - $100
Visit 3 - $100
Visit 4 - $100
Visit 5 - $195

The results from this study may lead to new commercial products or tests. If this happens you will not receive any compensation.

Statement of Consent:

Your signature documents your consent to take part in this research.

Signature of adult subject capable of consent	Date
Signature of person obtaining consent	Date

My signature below documents that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process	Date