Clinical Trial: Effects of Carboxymethylcellulose Artificial Tears on the Eye Microbiome

NCT: 05292755

Informed Consent Form 3/31/2022

• Principal Investigator: Yujia Zhou, M.D.

• Co-Investigator: Elizabeth Dawson

• Co-Investigator: Gary Wang, M.D., Ph.D.

• Supervisor: Walter Allan Steigleman, M.D.

UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position:_____

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the title of this research study (this "Research Study")?

Effects of Carboxymethylcellulose Artificial Tears on the Eye Microbiome: A Randomized, Controlled, Double-Blind Study

3. Whom do you call if you have questions about this Research Study (the "Study Team")?

Principal Investigator: Yujia Zhou - (305) 342-9166
Faculty Supervisor: Dr. Walter Steigleman - (352) 265-2020
Coinvestigator: Elizabeth Dawson (please call the above numbers)
Coinvestigator: Dr. Gary Wang (please call the above numbers)

4. Who is paying for this Research Study?

The sponsor of this study is the UF Ophthalmology Department.

5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

a) In general, what is the purpose of the research? How long will you be involved?

The purpose of this research study is to identify the effects of carboxymethylcellulose artificial tears on your eye bacteria. Carboxymethylcellulose is a common food and drug ingredient which affects the gut microbiome, but we have no knowledge of how it affects the eye. This experiment will analyze your eye bacterial population before and after using artificial tears and will last one week.

b) What is involved with your participation, and what are the procedures to be followed in the research?

At your first clinic visit, we collect an eye swab from both of your eyes and ask you to complete a short survey about any symptoms you may have related to dry eye. Afterwards, we will ask you to use a specific type of artificial tears for and return for follow-up to get a second eye swab and complete a second survey. This process involving follow-up will take one week from your first appointment to the second appointment. You will receive a week's supply of either Systane™ or Refresh™ artificial tears for free, but you will not be told which tears you have received.

c) What are the likely risks or discomforts to you?

You may encounter mild eye discomfort during conjunctival swabs, anxiety regarding assignment to a treatment group, short delays in clinic flow (1-2 minutes), and inconvenience of completing surveys during the study. Rare discomforts or risks may include breach of protected patient data, eye pain, dry eye, eye infection, and eye trauma including corneal abrasions and conjunctival hemorrhage because of methods used in this study. You will not be charged for any time, medication, or procedure used specifically for this study.

d) What are the likely benefits to you or to others from the research?

You will receive a week's supply of artificial tears or saline eye drops for free. We will use the information from this study to determine whether it is safe and effective to use carboxymethylcellulose artificial tears. Other people using artificial tears may be able to use this information to choose the right brand for them.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

You have the option to not enroll in the study and complete a normal clinic visit, where you will be treated for any eye ailments appropriately.

Additional and more detailed information is provided within the remainder of this Informed Consent form. Please read before deciding if you wish to participate in this study.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this Research Study)?

You will have a normal clinic visit at the UF Oaks Eye Center with a board-certified ophthalmologist and receive appropriate clinical care for your eye complaints. This may include antibiotics for eye infections, refractive prescriptions for refractive errors, and eye surgery as indicated by your conditions and symptoms.

7. What will be done only because you are in this Research Study?

You will receive a week's supply of artificial tears, complete two surveys on dry eye symptoms, and undergo two conjunctival swabs.

If any identifiable information or eye swabs are collected as part of this research, it is possible that your research information and eye swabs with all personally identifiable information removed, could be used

for future research studies, or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

If you have any questions now or at any time during this Research Study, please contact one of the Research Team members listed in question 3 of this form.

8. What identifiable health information will be collected about you and how will it be used?

The Research Team will collect:

- Name (will not be published or used in data analysis)
- Medical record number (will not be published or used in data analysis)
- Medical diagnoses
- Medication list
- Tobacco use status
- Age
- Sex

The Research Team may collect this information from other healthcare providers, such as laboratories, which are a part of this research, as well as healthcare providers that are not part of this research (other doctors, hospitals or clinics). Other professionals at the University of Florida or Shands Hospital who provide study-related care, and the University of Florida Institutional Review Board (IRB), may also collect your health information.

The Research Team listed in question 3 above will use or share your health information as described below to carry out this research study.

9. With whom will this health information be shared?

This health information may be shared with:

- The study sponsor (listed in Question 4 of this form)
- United States governmental agencies which are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections.
- Government agencies which are responsible for overseeing public health concerns, such as the Centers for Disease Control and federal, state and local health departments.
- the IRB that reviewed this Research Study and ensures your rights as a Study Subject are protected.

Otherwise, your identifiable health information will not be shared without your permission unless required by law or a court order. Once your health information is shared with those listed above, it is possible that they could share it without your permission because it would no longer be protected by the federal privacy law.

10. How long will you be in this Research Study?

You will be enrolled in this research study for one week, from your first clinic visit to your second visit.

This Authorization to use and share your health information expires at the end of the study unless you revoke it (take it back) sooner.

11. How many people are expected to take part in this Research Study?

Up to 80 people are expected to take part in this research study.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

12. What are the possible discomforts and risks from taking part in this Research Study?

Enrolled study participants may more commonly encounter mild eye discomfort during conjunctival swabs, anxiety regarding assignment to a treatment group, short delays in clinic flow (1-2 minutes), and inconvenience of completing surveys during the study.

Other possible risks to you may include breach of protected patient data, eye pain, dry eye, eye infection, and eye trauma including corneal abrasions and conjunctival hemorrhage because of methods used in this study

This Research Study may also include risks that are unknown at this time.

Please note, participating in more than one research study or project may further increase the risks to you. If you are already enrolled in a research study, please inform one of the Research Team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

During the study, the Research Team will notify you of new information that may become available and might affect your decision to remain in the study.

The University of Florida is required by law to protect your health information. Your health information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices, as required by University policy. However, there is a slight risk that information about you could be released inappropriately or accidentally. Depending on the type of information, a release could upset or embarrass you, or possibly affect your ability to get insurance or a job.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the Research Team members listed in question 3 in this form.

13a. What are the potential benefits to you for taking part in this Research Study?

You will receive free FDA-approved treatment (artificial tears) for dry eye during the study and improved guidance on artificial tear choice after the study's conclusion based on the study results. This may not benefit you if you do not experience dry eye. There are no other direct benefits to participants.

13b. How could others possibly benefit from this Research Study?

We will use the information from this study to determine whether it is safe and effective to use carboxymethylcellulose artificial tears. Other people using artificial tears may be able to use this information to choose the right brand for them.

13c. How could the Research Team members benefit from this Research Study?

In general, presenting research results helps the career of a researcher. Therefore, the Research Team listed in question 3 of this form may benefit if the results of this Research Study are presented at scientific meetings or in scientific journals.

13d. Will you be allowed to see the research information collected about you for this Research Study?

You may not be allowed to see the research information collected about you for this Research Study, including the research information in your medical record, until after the study is completed. When this Research Study is over, you will be allowed to see any research information collected and placed in your medical record.

14. What other choices do you have if you do not want to be in this study?

You have the option to not enroll in the study and complete a normal clinic visit, where you will be treated for any eye ailments appropriately.

You may also refuse to authorize the use of your health information, but if you refuse, you may not be allowed to be in this research study or receive any research-related treatment that is only available in this research study. However, your decision not to sign this Authorization will not affect any other treatment you may be eligible to receive.

15a. Can you withdraw from this study?

You may withdraw your consent and stop participating in this Research Study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. If you decide to withdraw your consent to participate in this Research Study for any reason, please contact the Research Team listed in question 3 of this form. They will tell you how to safely stop your participation.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Research Team listed in question 3 of this form to let them know your decision. If you take back this Authorization, the Research Team may only use and disclose your health information already collected for this research study. No additional health information about you will be collected or disclosed to the Research Team. However, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with a member of the Research Team listed in question #3.

15b. Can the Principal Investigator withdraw you from this Research Study?

You may be withdrawn from this Research Study without your consent for the following reasons:

- If you are diagnosed with an eye infection
- If you have not used any of the eye drops given in this study
- If you start taking any other eye drops containing carboxymethylcellulose
- If you start taking any other eye drops containing medication or preservatives
- If you start taking antibiotics

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

16. If you choose to take part in this Research Study, will it cost you anything?

You will not be charged for taking part in this research study. Any time, medication, or procedure provided solely for the purpose of this study will come at no cost to you. You will be charged for your clinic visit as if you were not taking part in this study.

17. Will you be paid for taking part in this Research Study?

You will not be pair or compensated for taking part in this research study. Artificial tears provided for this study are provided at no cost to you but are solely for the purpose of the research intervention.

18. What if you are injured while in this Research Study?

If you are experiencing eye pain, flashes of light, or loss of vision, call your emergency department or the UF Oaks Eye Center at (352) 265-2020. Otherwise, you will be treated at the Oaks Eye Center for your injuries and eye ailments during your normal clinic visit.

Please contact one of the Research Team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this Research Study.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this Research Study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

_____ _____

Signature of Person Obtaining Consent and Authorization Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described above. By signing this form, you are not waiving any of your legal rights.

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.

_____ _____

Signature of Person Consenting and Authorizing Date

INFORMED CONSENT FORM COVER SHEET

EFFECTS OF CARBOXYMETHYLCELLULOSE ARTIFICIAL TEARS ON THE EYE MICROBIOME: A RANDOMIZED, CONTROLLED, DOUBLE-BLIND STUDY

PARTICIPANT ID STICKER: