A universal eye drop adherence monitor to measure and improve adherence to ocular medications

NCT03506568

INFORMED CONSENT DOCUMENT

LEGACY HEALTH

Consent and Authorization Form for Research Study Approved by Institutional Review Board

Study Title: **A universal eye drop adherence monitor to measure and improve adherence to ocular medications**
Name of Investigator: Steven Mansberger, MD MPH
Research Team Contacts: Casie Goldman 503-413-6505 and Facundo Sanchez 503-413-6492
Study Sponsor: National Institute of Health

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study and about your rights and responsibilities as a research participant.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have any questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions, you understand the study and you decide that you want to be part of this study.
- You may take home a signed copy of this consent form for your records

WHAT IS THE PURPOSE OF THIS STUDY?

Glaucoma eyedrop medications are the most common method of treating glaucoma. The purpose of the study is to understand how patients use eye drops and how to improve eye drop usage in the future. We have developed a Devers Drop Device, that records the time and date when a patient removes the eye drop bottle cap from an eye drop bottle.

HOW MANY PEOPLE WILL PARTICIPATE?

This research study is looking for approximately 50 subjects.

WHAT WILL HAPPEN DURING THIS STUDY?

We will enroll 50 participants (25 male, 25 female) into a prospective trial with duration of up to 50 days. You will participate in an initial 25-day period to orient yourself to the device. We will ask you to use your Latanoprost eye drop at night using your normal routine.

After this 25-day period, you may be invited to continue for another 25 days. During this second 25 days, we will randomly (like flipping a quarter) assign you to continue your usual schedule, or a daily reminder using your smart phone and/or Devers Drop Device.

WHAT ARE THE KEY INCLUSION CRITERIA?

To be considered for enrollment into the study you must:

- Be over 18 years of age
- Give written informed consent
- Be prescribed Latanoprost eye drop to be used once per day at bedtime, own a functioning Android or Apple iPhone smartphone (iOs) with Bluetooth and cellular connectivity and have home Wi-Fi with simple password protection. Meet all of the additional relevant inclusion criteria
- Understand the study instructions, and be willing and able to follow the study instructions.

If you decide to be in this study, you may have to stop taking some of your other medications during the study. You can discuss this with your doctor.

WHAT ARE THE KEY EXCLUSION CRITERIA?

You will not be able to participate in the study if any of the following apply:
-Those with severe cognitive impairment limiting their ability to understand a questionnaire.

In addition to the above, the study doctor or study staff will discuss with you other reasons why you may not be eligible to participate in the study.

IS THERE A FINANCIAL INTEREST?

The Investigators (Mansberger/Kinast) for this study are also the inventors of the device being studied, and the device is the subject of a pending patent application. The device is used in this study with permission of the inventors. Please feel free to ask any questions about the Investigator's financial interest in this research.

HOW LONG WILL I BE IN THIS STUDY?

There will be a total of 3 study visits over a period of approximately 50 days. The study visits consist of one enrollment visit, one randomization visit, and one study exit visit.

WHAT HAPPENS WHEN I COME IN FOR STUDY VISITS?

The study doctor or study staff will do the things listed below when you come in for study visits. If you would like more information about which tests and procedures will be done at each study visit, ask the study doctor or study staff.

Before any study-related procedures are performed, the study doctor or study staff will talk to you about the study. You will then be asked to sign this consent form and the Authorization to Use and Disclose your Personal Health Information.

THIS PROCEDURE:	WILL BE DONE LIKE THIS:	DURING THIS VISIT:
Inclusion/Exclusion Criteria	The study doctor will confirm your eligibility to ensure you may be in the study.	Enrollment
Demographics	The study doctor or staff will ask you about your age, gender and race.	Enrollment
Medical history (General and Eye)	You will be asked about your general medical history. This includes your vision and eye health. This is a standard procedure.	Enrollment
Glaucoma adherence questionnaire	The study coordinator will administer the questionnaire to you.	Enrollment and exit
Diary	Each participant will receive a study diary to record difficulties, suggestions, and any other inputs they may have during the study.	Screening, patients will keep diary for duration of study

If you are eligible and enrolled into the study, you will take two questionnaires to determine adherence and demographics. We will provide the dose monitor and help you load an app on your smart phone. Your first dose using the monitor will be your first dose after the enrollment visit.

Each of your visits will be between 30 and 60 minutes.

If we are concerned the device is not working (i.e., if it has not communicated with us in 48 hours, we will contact you by phone to check on the device). This maximizes safety and decreases loss of data from device malfunction. The study doctor may request that you return to the clinical research unit at any time during your participation in this study for an unscheduled visit for additional examinations to ensure your safety and well-being. Additional examinations may include some or all of the assessments outlined above. The dose monitor must be returned at the conclusion of the study. We will ask you to fill out a survey and questionnaire to determine how well the device worked for you.

WHAT DO I NEED TO DO IF I DECIDE TO PARTICIPATE?

As a subject, you are responsible for following the study directions and those of your study doctor and study staff. This includes returning promptly to your study doctor's office for all necessary study follow-up visits, bringing the study medication with you for each treatment visit, reporting any changes in your medications (over-the-counter and prescription), reporting any

missed doses of the study medication, and reporting any changes in how you feel to the study doctor or study staff.

If you experience any illness or discomfort in the study, you should notify your study doctor or study staff. Your study doctor will then evaluate you to determine if you should continue the study.
During this study, you should notify any doctor who is taking care of you that you are participating in a research study that involves the use of this investigational product.
As a participant in this research study, you are expected to:

- Ensure that you do not take part in any other research study until this research study is concluded.
    - You can participate in this research study at a single location only.
    - Participating in another study could affect the results of this study. Your participation in this research study will immediately end if you decide to enroll in another research study.
- Keep the study device in a safe place that is away from children and pets. The study device must be used only by you, the person to whom it has been given.
- Contact the study staff and ask questions as you think of them.
- Tell the study doctor or study staff as soon as possible if you change your mind about staying in the study.

ARE THERE RISKS, DISCOMFORTS, OR INCONVENIENCES TO ME IF I PARTICIPATE IN THIS STUDY?

There are risks, discomforts, and inconveniences associated with participation in any research study. You should talk with the study doctor if you have any questions.
Please tell the study doctor or study staff right away if you have any problems with your health or the way you feel during the study, whether or not you think these problems are related to the study treatment.

Study Procedure Risks

We anticipate no additional risks to you in the study. All study subjects are already using the medications involved in the study. Because the dose monitor attaches to the bottle cap and the bottle cap-device combination is removed from the bottle tip in order to dispense an eye drop, the monitor will not alter eye drop delivery to the eye in any way. People using eye drops are always at risk of accidentally touching the tip of the bottle to their eye(s), which could cause pain and is a risk for any eye drop study. The dose monitor will not increase this risk. The eye drop monitor will record when you administer your eye drops and send the information to our research center. We expect no additional risks with our prototype device.

Loss of Confidentiality

There is a risk of loss of confidentiality of your information. You will read more about the protection of your information later in this form. Please ask the study doctor or study staff if you would like to know more about how your information will be protected while you are in this study.

Unknown/Unforeseen Risks

In addition to the risks listed above, there may be some unknown or infrequent and unforeseeable risks associated with the use of this study treatment. Since the study treatment is investigational, when taken alone or in combination with other medications, there may be other risks that are unknown. Tell the study doctor or study staff right away if you have any problems.

You will be informed verbally and in writing of any new information, findings, or changes to the way the research will be performed that might influence your willingness to continue your participation in this study. If you experience any side effects or research-related injury, contact Dr. Steven Mansberger immediately at 503-413-8202.

ARE THERE RISKS IF I AM PREGNANT, BECOME PREGNANT, OR FATHER A CHILD DURING THE STUDY?

No

IS THERE ANYTHING ELSE I CAN DO FOR MY CONDITION?

You do not need to participate in this study to have your condition treated. Glaucoma is typically treated with eye drops and/or with surgery.

WILL I BE INFORMED OF NEW INFORMATION?

You will be told of any important new information that is learned during the course of this research study that might affect your condition or your willingness to continue participation in this study. You may be asked to sign a new informed consent form.

CAN I LEAVE THE STUDY EARLY?

If you agree to participate in the study but then change your mind, you are free to withdraw your consent and stop your participation at any time without loss of benefits to which you are entitled. Should you decide to end your participation in this study, you must notify your study doctor that you wish to stop. It will be necessary for you to return to the study center for a final visit. During this study visit, the study staff will collect all study-related supplies, including unused study drugs, and your study doctor will assess your health before leaving the study. You can also discuss with your study doctor how to best continue your medical care. You may be asked to return to the study center after the final visit for safety assessments and follow up.

If you choose to leave the study early, you will not be able to withdraw any data that was collected about you prior to leaving the study. This data will remain in the study.

CAN I BE WITHDRAWN FROM STUDY?

The study doctor may withdraw you from the study without your consent for one or more of the following reasons:

- You do not follow the instructions of the study doctor or study staff, including failure to take the study drug according to schedule and/or appear at your scheduled appointments.
- The study doctor decides that continuing your participation could be harmful to you.
- You need treatment not allowed in the study.

- The study is cancelled by the Sponsor, the Investigative Site, a governmental agency (like the FDA), or for any other reason.
- Unanticipated circumstances or other administrative reasons arise that require the study to stop.

WILL BEING IN THIS STUDY HELP ME?

You may not receive any direct medical benefit from participating in this study.
Your participation in the study may benefit others with your disease or condition as a result of the knowledge gained from this research.

DO I HAVE ACCESS TO THE STUDY DEVICE WHEN THE STUDY IS OVER?

This product is investigational and is not available for purchase. Following your completion of or early termination from the study (for any of the reasons described above), you will no longer have access to the study device. If you choose to leave the study, you may no longer have access to the study device. Before leaving the study, you should discuss alternative therapies with the study doctor.

WHO WILL USE AND SHARE INFORMATION ABOUT MY BEING IN THIS STUDY?

Your identity will be kept confidential and you will not be identified by name, address, social security number or other country-specific identifier, or telephone number, except as disclosure is required by law or as described in this informed consent form.
Because the purpose of this research study is to obtain data or information on the study device, the results and/or data may be provided and/or reviewed by representatives of the:

- Sponsor, including its affiliates, agents and contractors
- Business associates working with the sponsor on the study (such as laboratories)
- Legacy Health IRB (the Research Ethics Review Board that reviews this study).
- Federal and other regulatory authorities (examples include the US Food and Drug Administration, European Medicines Agency, Health Canada, etc.)

Any of these parties may view your records; however, you will be identified only by a unique subject identification number, which should not identify you. Information about the subject identification number will be kept in a secure location with limited access.
The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity will not be disclosed in any of these meetings or publications.
A description of this clinical trial will be available on http://clinicaltrials.gov. This website will not include information that can identify you. At most the website will include a summary of the results for the study.

Images/Photographs/Videotapes

No photographs will be taken as a part of this study.

WILL I BE PAID FOR BEING IN THIS STUDY?

You may be provided compensation of $50 for your participation in this study.

WILL IT COST ANYTHING TO BE IN THIS STUDY?

It is not expected for there to be any costs to you for participating in this study. Items related to the routine medical care that you would receive even if you did not participate in this study will be billed to you or your insurance company.
If you have any cost-related questions or concerns, please ask your study doctor or study staff.

WHAT IF I GET HURT OR SICK WHILE I AM IN THE STUDY?

If you suffer any injury as a direct result of the study, and not due to the natural course of any underlying disease or the treatment process for such condition, and you have commercial or other non-governmental insurance benefits, reimbursement for all related costs of care will be sought first from your insurer or managed care plan.

If costs of care related to such an injury are not covered by your insurer or managed care plan, or are covered by a Federal or State benefits program, the Sponsor will pay for reasonable and necessary medical expenses that are a direct result of the study procedures or the study drug, and not due to the natural course of any underlying disease or the treatment process for such condition. The Sponsor will not pay for such expenses if you did not follow the directions of the study doctor and/or the study staff.

To pay these medical expenses, the Sponsor will need to know some information about you like your name, date of birth, and social security number or Medicare Health Insurance Claim Number. This is because the Sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare. The Sponsor will not use this information for any other purpose. Neither the Sponsor nor the study doctor will provide other compensation in the event of an injury. However, you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research.

WHO CAN ANSWER MY QUESTIONS ABOUT THIS STUDY?

Talk to the study doctor and staff about any questions or concerns you have about this study. You should also tell them about any side effects you have. Call the study doctor (Steve Mansberger) at (503.4138202).

You have a right to know about the risks, benefits, alternative procedures, and your rights as a research participant. If at any time you believe you have not been well informed, or if you feel pressure to take part in the study even if you do not want to, you can talk to a Research Specialist. Legacy Health's Research Regulatory Specialist Paul Newton, JD, CIP is available by phone during weekday working hours (8:30 a.m. to 5:00 p.m.) at (503) 413-5355.

CONSENT

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research.
- This authorization does not expire.

You may later change your mind and not let the research team use or share your information (you may revoke your authorization in writing).This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

_____ _____

(Signature of Participant) (Date)

_____

(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant. The participant has indicated that he or she understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)

_____

(Name of Person who Obtained Consent - printed)