



STRIDE

Strengthening Translational Research In Diverse Enrollment

**UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH**

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title: A Study to Compare the Benefits of Drug Absorption to Drug Delivery Using a Novel Device in Patients with Glaucoma

Sponsor: University of Massachusetts Medical School, Center for Visual Sciences

Investigator: Dr _____

Full address

Daytime Phone Number: 774-200-XXXX

24-Hour Phone Number: 774-200-XXXX

Consent Version: STRIDE 003 7.18.2018

You are being invited to take part in a research study. Someone will explain this research to you.

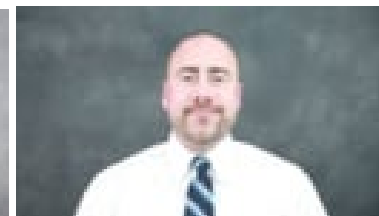
I would like to view stories about research participation



[Watch Angela's Story](#)



[Watch Darryl's Story](#)



[Watch Daniel's Story](#)

You are being invited to participate in a research study because you are 18 years old or older, and have advanced [glaucoma](#), vision of less than 20/200, and [intraocular pressure](#) of greater than 20mmHg.

If you have questions or don't understand something, please ask.

Taking part in this research is voluntary and completely up to you. You are free to say no or to leave the research at any time. There will be no penalties or changes in the quality of the health care you receive, and you will not lose any benefits to which you are otherwise entitled.

The main question this study is trying to answer is would a new delivery system for a known drug be more effective in lowering intraocular pressure for patients with advanced glaucoma.

If you join this research, you will be randomly assigned (like pulling a name out of a hat) to receive either:

- Group A: to receive ethacrynic acid eye drops OR
- Group B: to receive saline solution injection into the episcleral vein, using a new delivery device OR
- Group C: to receive ethacrynic acid injection into the episcleral vein, using a new delivery device

As part of the study, you will need to return for follow up for a physical exam. You will also be part of a focus group, to share your feedback with researchers about participation, barriers, and facilitators. You will give samples (saliva, blood, urine) and/or have physical exams and/or follow up sessions. Your participation in the study will end after the 12 months follow up. We will continue to collect information from your medical record for as long as 5 years.

You may not want to be in this study if you are uncomfortable with:

- The fact that neither you nor your doctor will get to pick which group you are in
- Sharing your private information with researchers
- You are concerned about the physical risks related to intravenous injection in the eye

Risks: We will take steps to protect your personal information. However, there is a risk of breach of confidentiality. There may also be risks that we do not know yet.

Benefits:

We cannot promise any benefits if you take part in this research. You may experience lowered intraocular pressure. Your participation will help the research team gain knowledge that may help treat glaucoma patients in the future.

Alternatives:

You do not have to be in this study to receive ongoing care from your doctor.

If you think you might like to participate in this research, please continue reading to learn more about the details of this study.

STUDY DETAILS

Why is this research being done?

The purpose of this research is to determine if there is a more effective way to reduce intraocular pressure in patients with glaucoma than absorption of topical ethacrynic acid. Researchers hope to show that injecting ethacrynic acid into the episcleral vein will work better.

How many people will take part in this research?

About 21 people will take part here at UMass Medical School.

What happens if I say yes, I want to be in this research?

If you participate in the study you will receive a single treatment for intraocular pressure (eye drops, saline injection, or ethacrynic acid injection), and experience eye examinations including intraocular pressure monitoring, and [eye exams using a slit lamp](#). You will be part of a focus group, to share your feedback with researchers about participation, barriers, and facilitators. You will also give samples (saliva, blood, urine) and/or have physical exams.

How long will I be in this research?

The table below outlines the timing and events that will occur as part of the study.

Timing	Study Event
Day -1	Eye exams (intraocular pressure/corneal epithelial)
Day 1	Treatment: Eye exam (intraocular pressure)
Day 2	Treatment: Eye exam (intraocular pressure)
Day 7	Treatment: Eye exam (intraocular pressure)
Day 30/1 Month	Physical exam, sample collection (blood, saliva, urine)
Day 42	Treatment: Eye exam (intraocular pressure/corneal epithelial)
12 Weeks	Focus group
6 Months	Sample collection (blood, saliva, urine)
9 Months	Sample collection (blood, saliva, urine)
12 Months	End of patient participation.
5 Years	End of possible span of time researchers monitor your medical record.



[Video of eye exam \(intraocular pressure\)](#)

- Study activities will take place at the UMass Memorial Center for Visual Sciences.
- You will be put into a study group by chance (like pulling names out of a hat). 7 people will be in Group A, 7 people will be in Group B, and 7 people will be in Group C. You cannot choose your study group.
- You will have outpatient visits at Day -1, Days 1, 2, 7, 42, for treatment, eye exams (intraocular pressure and corneal epithelial)
- The injection device (*Intraject*) is unapproved and experimental. Intraject device is an investigational device, meaning it is not approved by the Food and Drug Administration (FDA).
- *Intraject* may be available for continued therapeutic use after the research, pending results, but will not be covered by insurance.

Will you be collecting any specimens from me?

- No. The study will not require physical specimens.

Could being in this research hurt me?

The risks of this study are minimal to severe.

Minimal physical risk may include minor temporary discomfort during intraocular pressure monitoring, but would resolve quickly following the reading. Moderate physical risk related to the injection may eye injury, infection, bleeding, pain, ototoxicity, temporary loss of vision. Severe risk includes permanent vision loss. For participants who are women of child-bearing age, there are no known risks to the mother or the fetus. However, taking part in this may hurt a pregnancy or fetus in unknown ways. These may be minor or so severe as to cause death.

Psychological risks are minimal and may include potential anxiety about the injection.

Privacy risks are minimal, but there is a risk that someone could get access to the data we have stored about you. If those data suggest something serious about your health, it could be misused. For example, it could make it harder for you to get or to keep a job or insurance. There are laws against the misuse of genetic information, but they may not give full protection. We believe the chance these things will happen is very small, but we cannot guarantee they would not occur.

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

No, there is no cost to you.

Will I be given any money or other compensation for being in this study?

If participants will be paid:

You may be paid up to a total of \$700. Your compensation will be broken down as follows:

- Day 1: \$250, Day 7: \$100, Day 42: \$350
- If you drop out at any point in the study, no further payments will be made.

What happens if I am injured because I took part in this research?

If you are injured while in the study, seek treatment and contact the study doctor as soon as you are able.

If you are injured or have any harmful effects as a direct result of the Intraject device, or any procedure required by the research, necessary medical treatment will be made available to you at UMass Memorial Medical Center (UMMMC). The sponsor, will pay the reasonable and necessary medical costs for study-related injury.

To pay these medical expenses for a research injury, the sponsor will need certain information about you, such as your name, date of birth, and social security number. This is because the sponsor has to check to see if you receive Medicare. If you do, the sponsor must report the payment it makes to Medicare. The sponsor cannot use your information for any other purpose.

The sponsor has no plans to pay for medical expenses for injuries that are not directly related to your research participation or that are caused by the natural course of your disease. The sponsor has no funds set aside for any other form of compensation in the event of a research injury.

You do not give up any of your legal rights by signing this form.

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 protocol exactly, including attending scheduled sessions
- Alert your research team and doctor if you experience any unusual difficulty with your vision
- Refrain from using additional eye drops, using marijuana, or any other drugs known or suspected to impact intraocular pressure.
- Follow the directions of the study doctor and research staff.
- Tell your study doctor and staff about all prescriptions, over the counter medications, and vitamins or herbal supplements you are taking, and about all of your health issues.
- Tell your other health care providers that you are in a research study.

What happens if I say yes, but I change my mind later?

If you decide to leave this research, contact the research team so that the investigator can remove your name from the active roster.

If you decide to stop, we may ask if we can contact you for safety reasons or to follow your health. We may also ask you if we can collect data from your medical records and your routine medical care.

Data that we have already used will stay in the study database and cannot be removed in order to maintain the integrity of the research.

Can I be removed from the research without my approval?

The person in charge of this research study can remove you even if you want to continue. This may happen if:

- 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 take the research medication
- 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.

How will my information and specimens be stored and when will it/they be destroyed?

We will remove your name and any other information that could directly identify you from your data and specimens. We will replace this information with a code number. We will create a master list linking your code number to your name. We will keep this list separate from your data and specimens.

We will keep specimens and paper documents under lock and key. We will keep electronic health information and research data on secure computer networks. These computer networks have many levels of protection.

There is no limit on the length of time we will store your data and specimens. We will destroy the master list of identifiers at the conclusion of the study.

We will not use or share your data and specimens for any future research unrelated to this study, even if identifiers are removed.

It is possible that we might use the research data and specimens in other future research. We may also share data and specimens with researchers and companies that are not part of UMMS. In these cases, we will not share your name or other information that identifies you directly, and we will not come back to you to ask you for your consent.

Who has access to my information?

Signing this document means you allow us, the researchers in this study, and others working with us to use some protected health information for this research study.

As part of the research, UMass Memorial Medical Center or any other healthcare facility where you are treated may disclose the following information:

- Demographic and identifying information like your name, date of birth, address, telephone number, and your email address
- Related medical information like family medical history, and current and past medications or therapies
- Information from physical examinations, such as blood pressure reading, heart rate, temperature, height/weight, and lab results
- All tests and procedures that will be done in the study

In the event you die while enrolled in the study, all medical records related to your treatment and death at any healthcare facility will be released to Dr. Naomi Kendall and research staff.

Your health information and research records will be shared with the study team and with individuals and organizations that conduct or watch over this research, in order to conduct the study and to make sure it is conducted as described in this form. Information and records may be shared with:

- The research sponsor
- People who work with the research sponsor
- Federal and state government agencies, such as state auditors
- The Institutional Review Board (IRB) that reviewed this research

We will protect your identifiable information from disclosure to others to the extent required by law, but we cannot promise complete secrecy.

Any disclosure carries the potential for re-disclosure. Once your protected health information is disclosed, it may no longer be protected by federal privacy laws.

You may not be allowed to review some of the research-related information in your medical record until after the study is completed. When the study is over, you will have the right to access the information again.

Your authorization does not have an expiration date. If you change your mind, you have the right to revoke your authorization in writing or using the contact information at the beginning of this form. In such a case, you will not be allowed to continue to participate in the study. We will not collect any new information and may only use the information already collected for this research study. Your information may still be used and disclosed if you have an adverse event.

You do not have to sign this authorization. If you choose not to sign, it will not affect your treatment, payment, or enrollment in any health plans, or affect your eligibility for benefits. You will not be allowed to participate in the research study.

Will you share any results with me?

It may be several years before the results of the research are available. If you would like us to try to reach you at that time, please let us know. We will ask for your contact information.

We can share your individual results with you if you ask. However, because these are research tests, they are for your interest only. They cannot tell you about your health or diagnose any condition.

Who can I talk to?

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 on the first page.

This research is being overseen by an Institutional Review Board. An IRB is a group of people who perform independent review of research studies. You may talk to them at (508) 856-4261 or irb@umassmed.edu for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.

- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Signature Block for Capable Adults

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

Signature of adult research participant / date

Printed name of adult research participant / date

Signature of person obtaining consent / date