Permission to Take Part in a Human Research Study

University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Adult Consent to Participate in a Research Study

Title of research study: Outcomes comparison between Baerveldt 350 and Ahmed ClearPath 250 tube shunts for the treatment of glaucoma

Version Date: **19July2023**

Investigator: **Asher Weiner, MD**

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are being invited to take part in a clinical research study because you are being scheduled for glaucoma tube shunt implantation surgery.

You are therefore eligible to participate in this study evaluating the clinical outcomes of two different tube shunt devices namely Baerveldt 350 and Ahmed ClearPath 250 tube shunts. Both shunts are FDA approved and are commonly used for glaucoma surgery and none of them is experimental. There are no data available anywhere to determine which of these two devices has better outcomes.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

This research study will analyze the clinical outcomes of two different glaucoma tube shunts.

This type of glaucoma surgery (tube shunt implantation) is designed to help the natural fluid inside the eye to drain out of the eye more easily and thus reduce intraocular pressure. Multiple research studies have already shown that tube shunt implantation can be performed safely and can lower intra-ocular pressure to help stop glaucoma progression towards blindness.

What we don't know is which tube shunt of these two (Baerveldt 350 or Ahmed ClearPath 250) is more effective in lowering intra-ocular pressure, and which is safer for you.

Both tube shunts are FDA-approved and not experimental and are recognized as safe and effective glaucoma procedures, but there is no research that compares the clinical outcomes between these two devices. Thus, this research study is designed to compare between the Baerveldt 350 and Ahmed ClearPath 250 tube shunts. We hypothesize that the outcome will be similar using both devices.

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If you choose to participate in this study you will be randomized to receive one of these tube shunts during your upcoming surgery.

How long will the research last and what will I need to do? We expect that you will be in this research study for 2 years. The study is conducted as a part of your routine post-surgical clinic visits and no extra visits are needed or anticipated.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me? There is the known risk of surgical and post-operative complications and discomfort as in any routine eye surgery in general, and in tube shunt implantation in particular. However, a risk of research-related injury is not anticipated since this research is only collecting data on outcomes, not changing the procedures performed.

In general, the surgical procedures using either one of the two tube shunts in our study are similar. Performing tube shunt implantation for glaucoma is routine and considered standard-of-care and not experimental.

There is also risk of a breach of confidentiality of identifiable subject data. However, this risk is low as data will be stored on a network-connected, password protected computer. We will make every effort to preserve the confidentiality of your study data by using password-protected systems and associating your data with an assigned study number rather than your name.

Economic Risk: Since tube shunt implantation is a routine surgical procedure for glaucoma and not experimental you and your insurance company will be billed for the health care services that you would ordinarily be responsible to pay for. In some cases, insurance will not pay for services ordinarily covered because these services were performed in relation to a research study. You should always check with your insurance to verify which services will be covered by your insurance and which you will be responsible to pay for.

Will being in this study help me in any way?

We cannot promise any benefits from taking part in this research. However, possible benefits to you in the future and to others could emerge from assessing which tube shunt is safer or more successful in lowering intraocular pressure.

What happens if I do not want to be in this research?

Participation in research is completely voluntary and you may choose not to enroll in this study. Regardless of your participation in this study we will proceed with tube shunt implantation as routine standard-of-care provided to glaucoma patients like you at the Ross Eye Institute. You will continue to get services as usual without any interruptions.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 716-881-7900. You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

IRB Approval Period:

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This research has been reviewed and approved by an Institutional Review Board ("IRB"). An IRB is a committee that provides ethical and regulatory oversight of research that involves human subjects. You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your rights as a participant in this research
- 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 want to get information or provide input about this research.

How many people will be studied?

We expect about 70 people to participate in this study.

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

If you decide to participate in the research, the study will be described to you in detail and you will be asked to sign this consent to your participation.

The principal investigator, residents and the technicians will do all the necessary ocular evaluation and measurements. You will be scheduled for the tube shunt implantation and the surgical coordinator will give you details of the surgery schedule and procedure.

- The tube shunt implantation will be performed using one of the randomly assigned tube shunts in this study (either the Baerveldt 350 or the Ahmed ClearPath 250). You will be randomly assigned (like flipping a coin) to either of the treatments. You have a 50/50 chance of being assigned to either treatment group. The randomization is part of this research.
- You will continue Standard of Care medications as instructed by your Ophthalmologist before and after your surgeries. You will need to come for your usual post-surgical follow-up visits as part of your regular continuous medical (eye) care for a minimum of 2 years.
- Post-surgical visits are scheduled on day 1, week 1, 2, 3, months 1, 3, 6, 12, 18 and 24. More or less visits will be required depending on your glaucoma status and clinical course. All patients are scheduled for these visits irrespective of if they participate in the study or not.
- The team will assess surgical outcome by measuring visual acuity, intraocular pressure, visual field testing and ophthalmic imaging procedures, as required for your regular glaucoma care. No additional visits or tests will be needed beyond your regular care, regardless of your participation in this study.
- Your pre and post-surgical visits will be scheduled at Ross Eye Institute either at Downtown, Orchard park or Amherst locations depending on your preference and our availability. You can contact Ross Eye Institute 24/7, 365 days a year in case of an emergency.

Your EMR ID, gender, DOB, Age at Baseline, Race, Medical HX Pre –Op Diagnosis Glaucoma Stage Procedure and Procedure dates will be collected. The following data will be collected:

Pre-Op Findings include: Intra Ocular Pressure (IOP), Max IOP, Visual Acuity (VA), number of Medications, Cup-Disc Ratio, Visual Field parameters, OCT global RNFL and GCC, Central Corneal Thickness, Axial Length, Anterior Chamber Depth, Refraction (Sph Eq).

Post-Op Findings include: IOP, VA, number of medications, measured at least on Day1, Week1, 2,3 and Months 1, 3, 6, 12, 18 and 24. Cup to disc ratio and visual fields parameters

measured at least at month 6, 12, 18 and 24. OCT RNFL and GCC will be collected post-op at year 1, year 2.

Complications such as hypotony, corneal edema, hyphema, iritis, vit. hemorrhage and CME will be recorded. Additional information would include information about secondary procedures or surgery, and random notes.

The relevant research data from the patients EMR will be entered into a spreadsheet excluding private information and identifiers.

The data from these visits will be used for the purpose of research in addition to your regular care. The relevant study data from the clinical findings will be transcribed into a spreadsheet and stored in password protected electronic files on a desktop computer. The computer will be located in a locked office room of the principal investigator and research coordinator. Principal Investigator, Study Coordinator and other authorized research personnel involved in the study will have access to the data. The study related electronic file will be stored for at least 3 years or kept indefinitely if the PI desires, or deleted at the PI's discretion.

What are my responsibilities if I take part in this research? If you take part in this research, you'll have no additional responsibilities. You will be following up as usual per standard-of-care following glaucoma surgery.

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

You can leave the research at any time and it will not be held against you. If you wish to stop being in the research let the Principal Investigator know your decision regarding withdrawal. There will be no need for any withdrawal procedures because record collected during routine eye examination and follow-up procedures will be used for continued evaluation of the treatment provided as a part of standard-of-care. The study data collected up to the point of your withdrawal will be retained and analyzed. Any future clinical notes after study withdrawal will not be used for data analysis.

Is there any way being in this study could be bad for me? (Detailed Risks)

There is the known risk of surgical and post-operative complications and discomfort as in any routine eye surgery in general, and in tube shunt implantation in particular. However, a risk of research-related injury is not anticipated since this research is only collecting data on outcomes, not changing the procedures performed.

In general, the surgical procedures using either one of the two tube shunts in our study are similar. Performing tube shunt implantation for glaucoma is routine and considered standard-of-care and not experimental.

There is also risk of a breach of confidentiality of identifiable subject data. However, this risk is low as data will be stored on a network-connected, password protected computer. We will make every effort to preserve the confidentiality of your study data by using password-protected systems and associating your data with an assigned study number rather than your name.

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What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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

Federal law provides additional protections of your medical records and related health information. These are described in the HIPAA section of this document. Your information that is collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed. The research data extracted from medical records will be transferred to a spreadsheet and saved for up to three years, and will be destroyed after the data is analyzed.

Can I be removed from the research without my OK?

The principal investigator of the study can remove you from the research study without your approval. Possible reasons for removal include if you are unavailable for follow up visits and do not respond to contact requests. We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

You will not be compensated for participating in this study.

What medical costs am I responsible for paying?

The tests or procedures required by the research study that would not otherwise be part of your standard care will be covered by the sponsor of this study. The tests or procedures that would be provided to any patient with your condition, regardless of whether he/she was participating in the research study, are considered standard care and will be billed to you or your private or public health insurance company. You will still be responsible for the cost of your usual ongoing medical care, including deductibles and co-payments. If you have any questions about what expenses are covered by the sponsor and what expenses are the responsibility of you or your health insurance provider, please contact a member of the study staff and/or your health insurance provider.

Your private or public health insurance company (for example Medicare) will be billed for the standard of care device, the procedure to implant the device, and any other necessary procedures required by the study. You will be responsible for paying for any co-payment, co-insurance or deductible.

Who will pay for my medical care if participating in this research harms me?

It is important that you tell your study doctor if you feel that taking part in this study has injured you or caused you to become ill.

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You will receive medical treatment if you are injured or become ill as a result of this study. Your doctor will explain the treatment options to you and tell you where you can get treatment.

The University of Buffalo and Ross Eye Institute makes no commitment to provide free medical care or payment for any unfavorable outcomes that result from your participation in this research. Medical services will be billed at the usual charge and will be your responsibility or that of your third-party payer but 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 including The Ross Eye Institute/University at Buffalo.

By accepting medical care or accepting payment for medical expenses, you are not waiving any of your legal rights

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about you and about your health that will be obtained by the researchers when you participate in the research study. By signing this form, you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information and to use or disclose it for the purposes of the research described in this document. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What individually identifiable health information will be collected about you as part of this research study?

__X__ Information from your full medical records: Medical Record Number, Date of Birth, Date of Surgery, Pre-operative diagnosis and surgeries, surgical procedure, visual acuity, intraocular pressure, medications, visual field and ocular imaging reports.

__X__ New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

B. Who is authorized to create or provide this information for research use?

__X__ Principal Investigator or designee

__X__ Other(s) (identify): The Ross Eye Institute

C. Who is authorized to receive the information from the information providers identified in (B)?

__X__ Principal Investigator or designee

__X__ Other(s) (identify): Research Coordinator, Clinic staff at the Ross Eye Institute.

D. With whom may your protected health information be shared?

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

__X__ Clinical staff not involved in this research study who may become involved in your care if it is potentially relevant to your treatment

__X__ The organization(s) responsible for administering this research: The Ross Eye Institute, University at Buffalo, Department of Ophthalmology, The Research Foundation of the State University of New York.
__X__ The following: Principal Investigator, Research Coordinator and Statistician at the University at Buffalo.

Your information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

Although safeguards are in place to prevent accidental disclosure of your information beyond the purposes described above, the information disclosed through this authorization is no longer protected by HIPAA. There is the potential for this information to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

E. How long are the information providers listed in (B) authorized to provide your information for this research project?
This authorization will expire at the end of the research study. After that time, this authorization may not be used to acquire additional information about you. Your protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information.

F. What are your rights after signing this authorization?
You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about you will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s): Asher Weiner, MD
1176 Main Street
Buffalo, NY 14209

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

G. What will happen if you decide not to sign this authorization?

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Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

Should you agree to participate in this research, this consent document will be placed in your medical record.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research. By signing this form, you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

_____ _____

Signature of subject Date

_____ _____

Printed name of subject Date

_____ _____

Signature of person obtaining consent Date