WillsEye Hospital

Believing is Seeing

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An Educational Intervention to Increase Adoption of Selective Laser Trabeculoplasty as First-Line Treatment for Glaucoma

NCT03365778

Informed Consent Form for Patients

June 15, 2017

WILLS EYE HOSPITAL
INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY AND AUTHORIZATION FOR LIMITED USE AND DISCLOSURE OF HEALTH INFORMATION FOR THIS RESEARCH STUDY

Department: Glaucoma

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Medical Title: An Educational Intervention to Increase Adoption of Selective Laser Trabeculoplasty as First-Line Treatment for Glaucoma

Lay Title: Will additional education about laser treatment for glaucoma encourage patients to choose laser treatment over eye drops?

What Is an Informed Consent?

You are being asked to take part in a clinical research study. Before you can make an informed decision whether to participate, you should understand the possible risks and benefits associated with this study. This process is known as informed consent and means that you will:

- Receive detailed information about this research study.
- Be asked to read, sign and date this informed consent, once you understand the study and wish to participate. If you don't understand something about the study or if you have questions, please be sure to ask for an explanation before you sign this form.
- Be given a copy of this signed and dated form to keep for your own records.

Be aware that your relationship with the research physician bears certain differences from your relationship with your personal physician. Your personal physician individualizes the treatment of your specific problem with the expectation of a benefit to you. The research physician treats all subjects under a specific protocol to obtain

generalizable knowledge and on the premise that you may or may not benefit from your participation in the study. Be sure to ask questions of the study physician if you want further clarification of this relationship.

Introduction and Study Purpose

You are being asked to participate in this study because you have glaucoma. Glaucoma is a disease characterized by optic nerve damage, visual field defects, elevated intraocular pressure (IOP) and progressive vision loss. More than 3 million Americans have glaucoma and more than 150,000 are blind as a result.

Regular use of glaucoma medications can usually lower IOP, prevent disease progression, preserve vision and prevent blindness. However, many people with glaucoma do not always use their medication, with about one-third to one-half of patients with glaucoma not taking their drops as often as necessary, or have difficulty putting in the drops. There are also numerous local side effects from using them including red eyes, blurry eyes and dry eye symptoms. The systemic side effects range from triggering asthma, to lethargy and depression.

Selective laser trabeculoplasty (SLT), on the other hand, has been used safely and effectively for the treatment of elevated IOP in patients with open angle glaucoma for more than 20 years. SLT may result in mild and temporary IOP elevation, but this is a small risk and rarely of any significance. Other side effects include blurred vison and inflammation of the cornea (clear part of the front of the eye), but they are extremely rare.

The purpose of this study is to develop an educational program that will help improve your understanding of what laser treatment is, how it might be beneficial to you, and why it should be considered as the first glaucoma treatment to consider before the use of glaucoma eye drops.

Your participation in this study will last for one study visit (approximately one hour of your time). The entire study will last approximately 6 months. We hope to have 40 patients complete this study.

Procedures

If you agree to participate in this study, you will be randomly (like the flip of a coin) assigned to one of the following groups:

SLT Educational Intervention (20 Patients):

You will meet with your eye physician who will discuss both SLT and medication options for treatment of your glaucoma. After your eye examination, you will meet with a research coordinator who will ask you questions about SLT and glaucoma medications and your knowledge and opinions of both. You will then be given information to read about SLT and will be shown a SLT educational powerpoint presentation. After the presentation, you will be asked more questions about SLT and also will be given the opportunity to ask questions. If you decide to have a SLT, we will schedule the appointment.

NOTE: If you decide you would like to talk to your eye physician again about your treatment options, a message will be given to him/her and he/she will call you.

Usual Care Group (20 Patients):

You will meet with your eye physician who will recommend both SLT and medication options for treatment of your glaucoma. After your eye examination, you will meet with a research coordinator who will answer any questions that you have about treatment options. The research coordinator will ask you questions about SLT and glaucoma medications and your knowledge and opinions of both. If you decide at any point during the study that you want to have an SLT, you will be given a phone number to call to schedule it.

NOTE: If you decide you would like to talk to your eye physician again about your treatment options, a message will be given to him/her and he/she will call you.

Protecting Your Health Information

Wills Eye Hospital is committed to holding your health information in confidence and protecting it from unauthorized use and disclosure. Your health information includes, but is not limited to, your name, address, social security number, and other personally identifiable information as well as diagnosis, treatment, and other documentation. By signing this informed consent form, you are authorizing Wills Eye Hospital, its

Institutional Review Board, the principal investigator, and any other research personnel at Wills Eye Hospital to use your protected health information for purposes of this research study. Specifically, the following kinds of protected health information may be used or disclosed: demographic information such as your age, gender, and race; the results of your questionnaires as well as your medical history. Your name, address, and social security number are not included in disclosed research data and will not be published.

This authorization has no expiration date; however, you may revoke this authorization at any time, except to the extent that action has been taken in reliance on this authorization, by contacting the principal investigator at the telephone number on the front page of this form or by writing to the Privacy Officer of Wills Eye Hospital at 840 Walnut Street, Philadelphia, PA 19107. Since the use and disclosure of your protected health information is necessary for the conduct of this research study, revocation of this authorization will result in your withdrawal from this research study.

If you decide not to sign this authorization, you will not be allowed to participate in this research study. However, your decision to not sign this authorization will not affect your normal course of treatment at Wills Eye Hospital or insurance coverage.

It is possible that information disclosed under this authorization might be re-disclosed by the persons who receive it and no longer be protected.

Benefits to Subject

Even though you will not personally benefit from this research, there may be a benefit to society, in general, from the knowledge gained in connection with your participation in this study.

Payment

You will not receive payment for your participation in this study.

Voluntary Consent and Subject Withdrawal

You voluntarily consent to participate in this research investigation. You have been told what your participation will involve, including the possible risks and benefits. You may refuse to participate in this investigation or withdraw your consent and discontinue participation in this study without penalty and without affecting your future care or your ability to receive alternative medical treatment at Wills Eye Hospital.

Non-Waiver of Legal Rights Statement

By your agreement to participate in this study, and by signing this consent form, you are not waiving any of your legal rights.

I have read and received a signed copy of this 5 page informed consent form.

_____(Date)	_____(Date)
Your Name (please print)	Research Personnel Obtaining Consent
_____ Date)	_____(Date)
Your Signature	Signature of Research Personnel