Participant Informed Consent Form and Authorization to Use and Disclose Medical Information

TITLE: Clinical Comparison of Length of Cataract Procedures with Zeiss Lumera Versus Older Zeiss Microscope

PROTOCOL NO: TCZeiss
Clinicaltrials.gov NCT 03298841

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INTRODUCTION

You are being asked to participate in a medical research study. Before agreeing to participate in this research study. It is important that you read the following explanation of this research study. No guarantees or assurances can be made as to the results of the study.

The decision to participate in this study is up to you. Your participation is completely voluntary. Your decision will not affect your relationship with your regular doctor or your current or future medical care.

Please read this form carefully. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision whether to participate. Ask about anything you don't understand or would like explained better. Take time to decide whether or not you want to take part in this study and ask the study doctor or study staff as many questions about the study as you would like. You cannot take part in this research study until you sign this form.

This form explains the following:

- Purpose of the study
- Procedures involved in the study
- Possible benefits
- Possible risks
- How your medical information will be used and who may view it

Background and Purpose

YAG lasers are used in ophthalmology to correct cloudiness after cataract surgery, for some eye "floaters", and in some patients with glaucoma. Yag laser procedures can be done in the doctor's office, in an outpatient surgery center or in a hospital.

Most procedures are done sitting up. Some patients, like elderly people, children or those whose body types are not well suited to sitting up and getting close to the machinery may benefit from a new laser that is designed to allow patients to lie down while they receive these procedures. This laser is designed to provide the same treatments as traditional lasers but patients are able to lie down during the procedure.

PURPOSE OF STUDY

You are being asked to take part in this study because you have been diagnosed with cloudy capsule after cataract surgery or a specific type of glaucoma that requires a hole be placed in the iris or colored part of your eye in order to lower the pressure.

The purpose of this research study is to study the effects, safety and efficacy of this operating microscope in subjects who have a diagnosis of uncomplicatd cloudy lens or cataract.

This system has been cleared for use in Europe and the US as a medically therapeutic system.

Approximately 20 men and women between the ages of 18-85 will be enrolled in this study being conducted at Toyos Clinic's Nashville locations.

DURATION OF THE STUDY

Participation in the study will last approximately 3 weeks. During this period, you will receive a baseline visit and plan for cataract treatment, study treatment and one follow up visit at approximately 1 week post procedure.

YOUR RESPONSIBILITIES

If you agree to participate in the study, you will attend 3-4 visits at the clinic.

Screening visit: At this first visit, the study doctor will determine if you are eligible to participate in the study. The study doctor or staff will give you a detailed explanation about the study and review this consent document. Before any study-related tests or procedures are performed, you will be asked to read and sign this document. You may sign it at this visit or if you wish to have some time to think more about, consult with others, you may elect to take it home for as long as you wish. If you decide that you wish to participate in the study, you must return with a signed informed consent form within one week of the screening visit.

Baseline visit: After the informed consent is signed, you will be asked questions about your medical history or demographic information including age, gender, and race). This visit can occur on the same day as the screening visit or up to a week later. If you are eligible to participate in the study you will have a brief examination including:

Visual acuity test: the doctor or study staff will use a chart and ask them to read them from top to bottom as the letters become smaller.

Slit lamp exam: the doctor will examine the structures of the eye using a microscope and beam of light.

Glare test: the study coordinator or trained ophthalmic technician will
Study treatment: Each study visit will consist of the light device applied for 2 minutes to each lower central lid, each lower temporal lid and each upper temporal lid under the supervision of a trained investigator or sub-investigator. Study treatments will occur twice weekly for one month. Missed visits will be rescheduled as soon as possible.

Study assessments visits will occur once weekly at the 2nd treatment visit. The same procedures will be done at each study visit.

Procedures	Study Visit 1 Screening Day-7 to-1	Study Visit 2 Enrollment Day -7-0	Study Visit 3 Treatment	Study Visit 4 Post-procedure follow up

Informed consent	x			
demographics	x			
medical history	x			
Concomitant medicine review	x	x	x	x
bcva	x	x	x	x
Slit lamp exam	x			x
Gonioscopy if indicated	x			x
Glare if indicated	x			
Dilated ophthalmoscopy	x			X
Intraocular pressure	x			x

POTENTIAL SIDE EFFECTS AND RISKS

The treatment used in this study may cause all, some or none of the listed risks/side effects. There may be potential risks to you by taking part in this study including risks that are currently unknown.

Possible risks of this procedure include:

* inflammation of the eye or iritis
*floaters which may be temporary or permanent
*retinal detachment
*development of membrane on the back part of the eye
*swelling of the back part of the eye
*damage to the lens implant
*eye pressure going up or down temporarily

All laser treatments cause some amount of inflammation. Your doctor will discuss what medications should be used after the procedure and for what length of time.

Risks of procedures and tests for this study

You will have various eye examinations which may product temporary eye irritation.

-Slit lamp examination which allows an examination of the frontal eye structures of the eye, including the eyelid, sclera (the white of the eye), conjunctiva (a clear mucous membrane that covers the sclera just behind the iris), and the cornea. The instrument used for this test consists of a high-intensity light source that can be focused to shine a thin sheet of light into the eye.

-Dilated ophthalmoscopy, which allows examination of the back of the eye. The test may involve placing drops in the eye in order to dilate (expand) the pupils, which may cause you to experience some light sensitivity for a few hours after this examination. The dilating drops may rarely cause increased pressure in the eye leading to nausea and pain.

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Gonioscopy – if it is necessary to diagnose your glaucoma condition your doctor will place a lens on the front of the eye after an anesthetic drop is placed in the eye. A thick solution may or may not be used to assist your doctor in seeing. Your doctor will slowly turn the lens in a circle over your eye to see the important structures there.

Glare – the study coordinator or designated ophthalmic technician will shine a light in your eye to determing if glare is a significant problem for you.

Intraocular pressure – a strip of dye moistened with anesthetic may be touched to the front of your eye or a dye drop with anesthetic mixed in will be placed in your eye. A qualified technician will use an instrument that touches the front of your eye lightly to measure pressure. Alternatively, an anesthetic drop and a handheld unit that lightly touches the front of your eye may be used to measure pressure.

Pregnant women are not eligible to take part in the trial. If you are a woman who may become pregnant, you must use an effective method of birth control while participating in the study and for four weeks after your last dose of study drug. If you become pregnant during the study, please let your study staff known immediately and cease use of the study product. If you become pregnant during the study, the study staff will ask to follow your pregnancy to its outcome. You should tell your study doctor about physical or emotional changes or side effects that may occur while taking part in this study. Promptly report any health problems or changes to a member of the study staff or your study doctor.

New Findings
We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

Potential Benefits
You may benefit as a result of your participation in this study. However, there is no assurance that you will benefit from your participation in this study. Results from this study may benefit other patients in the future.

Your cloudy capsule or glaucoma may worsen, improve or stay the same while receiving the study treatment.

Alternative Treatment
This clinical study is for research purposes only. You do not have to participate in the study to receive treatment for cloudy capsule or angle closure glaucoma. There are other options available to you including using a regular YAG laser that you sit up to receive or surgery. You may choose to take part in a different study, if one is available and for which you may be eligible.

Costs

There will be no charge to you for your participation in this study. Study-related procedures and study visits will be provided to you at no charge or to your insurance company. If you are injured or get sick because of being in this research, call the study doctor immediately. The study doctor will provide emergency medical treatment. Your insurance may be billed for this treatment. No other payment is available from the study doctor.

You will not be paid for being in this study.

Voluntary Participation/Withdrawal
Your decision to participate in this clinical research study is voluntary. You may choose not to participate or you may withdraw from the study for any reason at any time without penalty or loss of any benefits you are otherwise entitled. You should tell the study doctor or study team if you decide to leave the study.

The study doctor can stop the study or your participation in the study at any time without your consent if it appears to be medically harmful to you, if you fail to follow directions for participating in the study, if the study is canceled, or for administrative reasons. If you withdraw or are withdrawn from the study, you will no longer receive access to study product but may be asked to continue in the study for safety measures.

Confidentiality
Your identifiable health information is protected by a federal law called Health Insurance Portability and Accountability Act of 1996 (HIPAA). You will be asked to review and sign a separate HIPAA authorization form.

Information from this study will be given to the sponsor. “Sponsor” includes any persons or companies that are contracted by the sponsor to have access to the research information during and after the study.

It is possible that regulatory agencies such as the U.S. Food and Drug Administration (FDA) may inspect confidential study materials and absolute confidentiality cannot be assured. However, all medical records and research materials will be held confidential to the extent permitted by law. Medical records which identify you and the consent form signed by you may also be looked at and/or copied for research or regulatory purposes by:

1. Department of Health and Human Services (DHHS) agencies
2. The institution where the research is being done, and
3. Western Institutional Review Boards (WIRB).

If the results of this study are published or presented at meetings, you will not be identified. This permission or authorization has no end date. You have a right to see your study records but will not be able to do so until the study has ended.

You may withdraw your permission at any time by writing your study doctor a letter. If you withdraw permission after you have entered the study, you cannot continue participating in the

study. If you refuse to give permission or withdraw permission, your medical care and relationship with your health care providers at the study center will not be affected.

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 above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (800) 562-4789, help@wirb.com if:

You have questions, concerns, or complaints that are not being answered by the research team
You are not getting answers from the research team.
You cannot reach the research team.
You want to talk to someone else about the research.
You have questions about your rights as a research subject.

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.

Consent

I have read the statements in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study, if and until I decide otherwise. I do not give up any of my legal rights by signed this consent document. I may request a copy of this signed consent document.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date

I have carefully explained to the participant the nature and purpose of the above study. There has been an opportunity for the participant to ask questions about this research study. I have been available to answer any questions that the participant has about the study.

Printed Name of Person Conducting Consent Discussion

Signature of Person Conducting Consent Discussion

Date

Authorization to Use and Disclose Protected Health Information

During your participation in this research study, the study doctor and study staff will collect or create health information about you and record it on study documents. The study doctor will keep this protected health information.

Under federal law, your protected health information (PHI) that is created or obtained during this research study cannot be used or disclosed without your permission. This permission is called an "Authorization." You do not have to sign this Authorization, however, you may not participate in this study unless you give your permission to use and disclose your PHI by signing this authorization. By signing, you are agreeing to allow the study doctor and study staff to use your health information to conduct this study.

This Authorization will never expire unless and until you revoke (cancel or withdraw) it.

You have a right to revoke your Authorization at any time. If you revoke it, your health information will no longer be used for this study, except to the extent the parties have already taken action based upon your prior Authorization or need the information to complete analysis and reports for this research. To revoke your Authorization, you must write to the study doctor, state that you are revoking your Authorization to Use or Disclose Protected Health Information. The study doctor's mailing address is Toyos Clinic, 2204 Crestmoor Road, Nashville, TN 37215. If you revoke this Authorization, you will not be allowed to continue in the study.

You may receive a copy of this Authorization after you have signed it.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date

I have carefully explained to the participant the nature and purpose of this form. I have been available to answer any questions that the participant has about this form.

_____

Printed Name of Person Obtaining the Authorization

_____ _____

Signature of Person Obtaining the Authorization Date

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