Adaptive Optics Retinal Imaging

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Study Sites: Optical Diagnostic Devices Laboratory
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University of Maryland Eye Associates (UMEA)
2101 Medical Park Drive
Silver Spring MD 20902

Introduction

You are invited to participate in a research study to assess a new type of high resolution retinal imaging technology that uses adaptive optics (AO). AO senses the way your eye distorts light and corrects imaging beams to allow very sharp pictures of the back of your eye (the retina) to be taken. This technology may eventually be used to help diagnose and treat eye diseases. The AO imaging devices used in this study are investigational devices, which means that they have not received FDA approval. Please ask the research staff to explain any part of this form that is not clear to you. Before you decide if you would like to volunteer you should completely understand the possible risks and benefits of the study. After reading this consent form, having the study fully explained to you, and having all of your questions answered, if you agree to participate in the study, you will be asked to sign this form.

Purpose of this Study

The purpose of this study is to evaluate novel high-resolution adaptive optics imaging technology, including new hardware, processing and analysis software algorithms, and methodology that may be beneficial in detecting and treating eye disease.

Test Protocol and Duration

The study will take place in a research laboratory on the White Oak Campus, Building 62, Room G238 (Non-FDA employees: see accompanying map for directions and security checkpoint instructions). We expect to enroll up to 80 subjects, 30 of whom have primary open angle glaucoma (POAG). You will be asked to attend one or more imaging sessions. For both FDA and non-FDA employees, the sessions can be scheduled to occur anytime that meets your schedule (including weekends). If you are an FDA employee, the sessions must occur when you are off duty (i.e., during leave or credit time). The maximum number of sessions per year will be five and the minimum time between sessions will be one week.

At least one week prior to the first imaging session at FDA, you will receive a full eye exam by an ophthalmologist at the University of Maryland Eye Associates (UMEA) to help assess any risks, especially of the dilating drops. For FDA employees, the eye exam will be free. For non-FDA employees recruited from the UMEA clinic: the eye exam and all associated testing procedures are part of your routine care and will be billed to your insurance.

For this study, we use the term ‘eye exam’ to mean the initial screening exam at UMEA and ‘imaging session’ to mean imaging on the investigational AO retinal imager at FDA. Both the UMEA eye exam and the FDA imaging session will take approximately 2 hours (not including recovery from dilation). Generally, we will dilate and image only one eye for the imaging sessions (the same eye each time) but both eyes will be dilated and checked at the eye exam. For both the UMEA eye exam and the FDA imaging session, Tropicamide 1% will be used to dilate your eyes. Photophobia (sensitivity to light) from enlarged pupils will occur after both the eye exam and imaging session and you will be given disposable sunglasses to wear until the dilating drops wear off (~4-6 hours after administration). Until the eye drops wear off, you should not drive or participate in any other activity where vision is needed to avoid hazards. You may wish to bring someone with you to the exam to provide transportation.

UMEA Eye Exam

For the eye exam, instillation of a topical ocular anesthetic (Proparacaine 0.5%) and topical fluorescein are required to check intraocular pressure and perform gonioscopy (examination of the angles in your eyes) as per routine office protocol. If there is no risk for angle closure, your eyes will be dilated with the topical drug Tropicamide 1%. For subjects with healthy eyes, the eye exam will include baseline imaging and biometry (eye length) measurements with marketed devices. For POAG subjects, the eye exam may include baseline imaging, biometry, and perimetry (visual field) measurements with marketed devices. The baseline imaging includes fundus photography and optical coherence tomography (OCT), two different ways to collect images from the back of your eye.

After the eye exam, an ophthalmologist will assess the risk to you of further participation and you may be excluded if the risk of reaction to the eye drops, as determined by the ophthalmologist, is high. You may also be excluded from further participation if you meet the exclusion criteria, which includes predisposition to (i.e., narrow iridocorneal angle) or any history of acute angle closure glaucoma (AACG), visual correction outside the range +4 diopters (D) to -8 D, eye pathology that prevents imaging, or if you do not meet the criteria for POAG as defined by the American Academy of Ophthalmology Practice Patterns (for POAG subjects only). Your eyes will be observed for 30 minutes by a certified ophthalmologist to determine if you have a reaction to dilating drops. If you do, clinic staff will administer any necessary treatment.

FDA Imaging Session

Once you have been screened and cleared by the ophthalmologist to continue participation in the study, we will schedule you for an imaging session. During each imaging session, you will be given eye drops (Tropicamide 1%) by trained research staff to dilate your pupils. The eye drops are necessary to collect optimal images, and if you are uncomfortable receiving them or know of any history of reaction, you should not participate in the study. Staff will monitor your eyes in general during the entire imaging session for any adverse events.

After your pupils dilate, you will be asked to sit and place your chin on a rest to stabilize your head and look into the imaging instrument. While looking into the instrument, you will observe several lights. The investigator will describe what you will see and give you instructions on what to look at. The investigator may also ask you to periodically blink. Beams of light will be directed to your eyes to take images of your retina. At no point will anything touch your eye. You will be given rest periods after scans to avoid fatigue where you will be asked to sit back from the instrument. You may ask for additional rest periods at any time during the experiment. During the imaging sessions, video sequences of different regions of your retina will be collected.

You may be asked prior to signing this consent form to participate in an image test that uses visible light to stimulate your retinal cells. If you agree, visible light pulses at eye-safe levels will be delivered to your eye during the imaging session. You may decline to participate in the test involving visible light stimulation but still participate in a standard imaging session.

You may be asked prior to signing this consent form to participate in an image test designed to measure your retinal blood flow. This involves wearing a face mask during imaging and continuously breathing oxygen. Also, we will use a standard pulse oximetry device clipped to your finger, blood pressure monitoring using a blood pressure cuff, and an ECG monitor which uses ECG leads on your chest to monitor heart rate and blood oxygenation (the concentration of oxygen in your blood). Other than wearing a mask and finger clip, the imaging session will be conducted very similarly to that described above. You may decline to participate in the retinal blood flow testing but still participate in a standard imaging session.

You may be asked to have your eyes imaged with an investigational high-resolution OCT device. This device is identical in form and function to the FDA-cleared Heidelberg Spectralis OCT system except changes to the source and scan size to achieve high resolution OCT images. You may decline to participate in the high-resolution clinical imaging but still participate in a standard imaging session.

Potential Risks and Discomforts

Participating in research may result in an injury. If you suffer an injury directly related to your participation in this study, the study researchers will help you obtain medical treatment for the specified injury. If for any

unforeseeable reason you notice changes in your vision after the eye exam or imaging session, contact the PI and if you feel the severity of the changes to your vision are significant, you can request and will receive an additional eye exam by Dr. Saeedi at UMEA at no cost to you. The study researchers have not set aside funds or reimbursement for the cost of care provided to treat a research-related injury or for other expenses arising from a research-related injury. The institution or group providing medical treatment will charge your insurance carrier, you, or any other party responsible for your treatment costs. If you incur uninsured medical costs, those costs will be billed directly to you.

The potential risk of injury from participation in the study include: (1) risk of reaction to the dilating eye drops (increase in intraocular pressure), (2) risk of exposure to light levels that can lead to eye injury, (3) risk of injury from exposure to laboratory instruments, and (4) risk of airflow restriction and side effects associated with breathing oxygen continuously. This study may also involve risks that are currently unforeseeable.

The eye drops administered are safe for almost everyone and are commonly used by optometrists and ophthalmologists. You may feel a brief burning or stinging sensation when the drops are first placed in your eyes; this is normal. If you know of any history of reaction to pupil dilating drops, you should not participate. You will also notice a higher sensitivity to light after the exam, and you should avoid outdoors and bright lights. Sunglasses will be provided for use until the drug wears off (typically within 4-6 hours of administration). Other adverse reactions (from the drug label information) include dryness of the mouth, tachycardia, headache, allergic reactions, nausea, vomiting, pallor, central nervous system disturbances and muscle rigidity.

All light levels from the imaging and stimulus beams are accurately measured each day before any subjects are imaged and are below maximum safe power level established by the American National Standards Institute (ANSI standard Z 136.1 – 2014).

Possible side effects from breathing oxygen continuously include dry nose, bloody nose, fatigue, or headaches. Your comfort along with oxygen saturation levels will be closely monitored using standard pulse oximetry. If you exhibit any side effects, we will terminate the experiment immediately.

There is also a risk of accidental disclosure of your private information. See the Confidentiality Section below on the steps the study investigators have taken to mitigate this risk.

Possible Benefits of and Alternatives to Participation

There is no direct benefit of participation to you. You will receive no treatment. However, results from the study may help improve high resolution AO retinal imaging technology, and how it is evaluated by the FDA, which may provide a benefit to future patients with eye disease (including POAG). If you are a subject recruited from UMEA, your clinical care will not be affected in any way if you choose not to participate or withdraw from the study.

There are no alternatives to participation, beyond choosing not to participate.

Confidentiality

This research is covered by a Certificate of Confidentiality issued by the FDA. The study researchers (listed above) may not disclose or use information, documents, or data that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence unless you have consented for this use. Information, documents, or data protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure; if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the FDA which is funding this project or for information that must be disclosed in order to meet the requirements of the FDA. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

Your participation and all records obtained from this study will remain confidential to the extent permitted by law. For the initial UMEA eye exam, records will be kept at the eye clinic in the same manner as records from patients in the clinical practice. Most patient information is recorded in paper files that are kept in locked cabinets. Some information is collected in encrypted electronic records, which are stored on password protected computers. All patient information remains on-site at the UMEA eye clinic and is accessible only by trained staff and maintained with confidentiality abiding by HIPAA and all relevant regulations regarding medical records. With your permission (granted by signing a separate, additional HIPAA authorization form), some clinical data from the eye exam may be transferred to the FDA investigators. All transferred clinical data will be labeled with a code and will not contain your name or other information directly identifying you. Access to this data is limited to the study researchers listed above. Your records for the initial eye exam will be kept together with records from the clinical practice and destroyed seven (7) years after initial collection.

For the FDA imaging session, the only identifying information we will collect is your name and age, and we will keep this information confidential. Your name and age will not be stored with your images or data. Documents containing any identifying information, including this form, will be kept in a locked file cabinet and destroyed five (5) years after study termination. Servers and computers where the images and data are stored are password protected.

The images and data will be used publicly for research and educational purposes, including in publications and presentations, and may be viewed by internal and external professional colleagues, students, and other trainees. When we disclose information about this research to the public, we will take steps to ensure that the images or data disclosed cannot be linked back to you (e.g., deidentification) so that confidentiality will be maintained.

Participation and Withdrawal

Your participation in this research is completely voluntary. You may choose not to take part at all. If you decided to participate in this research, you may withdraw from the study at any time by notifying the PI. You may choose not to participate in the retinal blood flow testing but participate in a standard imaging session. If you decide not to participate in this study or end participation, you will not be penalized or lose any benefits to which you otherwise qualify. If you are an FDA employee and decide not to participate or end participation, your employment status will not be affected. If you are an UMEA patient and decide not to participate or end participation your UMEA medical care will not be affected. The investigators may also end your participation in this study if he or she feels that your participation presents any safety concern or if you do not meet the inclusion criteria. You will be informed if any significant new findings are discovered that may affect your willingness to participate in the study.

Compensation and Costs

You may receive a gift card to compensate for travel expenses. There are no costs for your participation in the study.

Rights as a Research Subject

If you have any questions about your participation in the study you may call or email the principal investigator, Daniel X. Hammer, Ph.D., at (301) 796-9320 or daniel.hammer@fda.hhs.gov.

The Food and Drug Administration Institutional Review Board (IRB) oversees all FDA human subject studies and ensures that the rights of research participants are protected. The FDA IRB has reviewed this research study and may review the records of your participation in this research to ensure that proper procedures are followed.

If you have questions about your rights as a study participant or concerns about how you are treated in the study, you may contact FDA Human Subject Protection Program at 301-796-9605 or HSPPMS@fda.hhs.gov.

You have not waived any legal right to which you are legally entitled by signing this form.

Consent Statement

I have read the above statements and have been allowed to ask questions and express concerns that have been satisfactorily answered and addressed by the research staff. I understand the purpose of this study as well as the potential benefits and risks involved. I hereby give my informed and free consent to participate in this study. I have been given a copy of this consent form.

Subject Name:_____Subject Signature: _____Date:_____

Investigator's Signature:_____Date:_____Subject # _____