COMIRB
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Principal Investigator: Dr. Cristos Ifantides
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Study Title: Enhanced Pupil Dilation in Patients Taking Alpha-Blockers for Potential Treatment of Intraoperative Floppy Iris Syndrome

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You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about the ability of Brimonidine, a topical alpha agonist medication, to treat Intraoperative Floppy Iris Syndrome.. Intraoperative Floppy Iris Syndrome (IFIS) causes poor pupil dilation and most often occurs in patients who take medication for BPH, such as Tamsulosin. IFIS results in increased risk of of complications during eye surgery. .

You are being asked to be in this research study because you have been prescribed Tamsulosin (Flomax) or another medication similar to it (an alpha blocker) at some point in your life and this puts you at increased risk for having IFIS, which would be diagnosed during eye surgery.

Other people in this study

Up to *30* people from your area will participate in the study.

What happens if I join this study?

If you join the study, you will be asked to come to Denver Health Eye Clinic for a pupil examination and then pupil dilation with the standard pre-operative pupil dilation medications. The investigator will measure your pupil size before instilling the drops, and then 15, 25-30, and 45 minutes after instilling the drops.

While the dilation effects of these drops are usually subsided after 24 hours, we will wait 3 weeks before prescribing the next medication.

At 3 weeks into study participation we will prescribe you Brimonidine Tartrate .2% to be applied to your RIGHT eye 3 times each day for a total of 7 days.The investigator will show you how to properly put these drops in your right eye. This will dilate the pupil of this eye for the entire 7 days.

Once you complete all 7 days of eye drops to the right eye, you will return to the eye clinic for pupil dilation a gain. The investigator will measure your pupil size, instill the dilating drops, and then re-measure post-dilation pupil size.

No procedures done in this study are done as part of your routine eye care. All study procedures are research related only.

Optional Additional Study Procedures:

If you would like to be contacted for future research opportunities, the investigator would like to add your name and contact information to a "potential future study database". This database will be maintained by the study PI, and only he will have access to your information for contacting for future studies.

Please select your choice:

☐ Yes, Please add my name and contact information to the Future Research Database

☐ No I do not want to be contacted for future research

What are the possible discomforts or risks?

Discomforts you may experience while applying brimonidine tartrate .2% for 7 days include transient burning, stinging, itchiness, dryness, or other eye irritations. You may also develop swelling around the eye or eyelid, red eye, eye tearing, visual disturbances. Other temporary side effects that have been reported include systemic symptoms such as stomach aches, diarrhea, constipation, fatigue or increased tiredness, increased sadness/depression, or decreased sleep/insomnia.

During the study visits when you are given the dilating compound composed of cyclopentate 1%, tropicamide 1%, and phenylephrine 1%, you may experience transient burning, stinging, irritation, and visual disturbances. This medication may also cause temporary headache, dry mouth, red eye, increased heart rate of blood pressure.

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it can not be guaranteed.

If you become pregnant, the particular treatment or procedures involved in the study may involve risks to the embryo or fetus which are currently unclear. Treatment should be stopped.

The study may include risks that are unknown at this time.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about brimonidine tartrate's ability to treat IFIS compared to the current standard of care. This study is not designed to treat any illness or to improve your health. Also, there may be risks, as discussed in the section describing the discomforts or risks.

Will I be paid for being in the study?

You will be paid $50.00 for each visit in this study. This will add up to a total of $100.00 if you complete all of the visits If you leave the study early, or if we have to take you out of the study, you will be paid only for the visits you have completed.

It is important to know that payments for participation in a study is taxable income.

Payments for taking part in this research study will be put onto a "ClinCard". ClinCard is managed by a company named Greenphire. ClinCard works like a gift card and can be redeemed where Mastercard is accepted. At a minimum, your name, date of birth and social security number will be given to Greenphire in order for study payments to be loaded onto a ClinCard. Let the research staff know if you have concerns about using ClinCard.

It is important to know that payments for participation in a study is taxable income. If you receive $600 or more from Denver Health & Hospital Authority in one tax year, you will be sent an IRS Form 1099 for tax purposes.

Will I have to pay for anything?

We will provide the study drug at no cost during this study. Tests and procedures that are done only for the study will not be billed to you or your insurance company.
You or your insurance company may be billed for:

- Any standard medical care given during this research study.

You may want to talk with your insurance company about its payment policy for standard medical care given during a research study. If your insurance company does not pay, you may be billed for those charges.
You might have unexpected expenses from being in this study. Ask your study doctor to discuss the costs that will or will not be covered by the sponsor. This discussion should include who will pay the costs of treating possible side effects.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason.

What happens if I am injured or hurt during the study?

If you have an injury while you are in this study, you should call Dr. Ifantides immediately. His phone number is *(303) 436-4949.*

We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Cristos Ifantides. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Ifantides at (303) 436-4949. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. Ifantides with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

A description of this clinical trial will be available on http://www.Clinical Trials.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.

Who will see my research information?

The University of Colorado Denver (UCD) and its affiliated hospital(s) have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include

- University of Colorado Denver
- Denver Health

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the UCD and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Cristos Ifantides, MD, MBA
700 Delaware St
Pavillion D
Denver, CO 80204

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:.

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator. [To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study is completed].

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity)
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical
- Research Visit and Research Test records

HIPAA Authorization for Optional Additional Study Procedures

In this form, you were given the option to agree to additional, optional research procedures. You must also give us your permission, under HIPAA rules, to use and disclose the information collected from these optional procedures, as described above.

If you decline to give us permission to use and disclose your information, you cannot take part in these optional procedures, but you can still participate in the main study. Please initial next to your choice:

_____ I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

_____ I **do not** give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____