

**RANDOMIZED TRIAL TO EVALUATE THE EFFICACY OF A SMALL VOLUME
TOPICAL OPHTHALMIC SPRAY FOR PUPILLARY DILATION IN CHILDREN**

Protocol Number:	20-32530A
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Intervention:	MydCombi® (Eyenovia, Inc., New York City, NY)

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

ASSENT TO PARTICIPATE IN A RESEARCH SUBJECT **Efficacy of the Various Device on Pupillary Dilation in Clinic and Intraocular** **Pressure Reduction in Patients with Glaucoma** **For adolescents 13-17 years old**

What is this study about?

Julius Oatts, MD from the UCSF Department of Ophthalmology is doing a research study. The study will look at MydCombi, a spray formulation for pupil dilation.

The study doctor hopes to find out if MydCombi and standard eye drops have the same effects as normal eye drop administration, but we don't know this will for sure. We are looking at are eye drops for pupil dilation. That's why we're doing the study.

The doctor is asking if you want to be in this study because you are receiving a routine dilated eye examination in the clinic.

How many people will take part in this study?

About 50 children and adolescents (0 to 17 years old) and 50 adults (18+ years old) will be in this study from UCSF.

What will happen if you decide you might want to be in this research study?

First, your parents will be asked if they give their permission for you to be in this study. They will also be asked if they agree to participate themselves, by doing some things like answering questions about you. If your parents don't agree, you cannot be in the study. If your parents do agree, and you agree too, you will do the following things below.

What will happen in the study:

1. The study doctor will ask your parents some questions about you.
2. The study doctor will ask you questions about your health.

If you are in the dilation part of the study, the doctor will dilate one of your eyes with the MydCombi and one the normal way and determine if there is a difference in your pupil dilation after 30 minutes.

Will any parts of this study hurt or have other risks?

The eye drops might give you a small amount of discomfort or irritation, but this will go away after a short while.

Will you get better if you are in this study?

We don't know if this study will make you feel better. You may get a little better by being in this study, or you may stay the same, or you may get worse.

What if you have questions?

You can ask Dr. Oatts or the people who work with him any questions you have about the study. You can ask your questions now or later, any time you like. You can also ask your parents to ask questions for you.

What are your choices?

If your parents agree, you can be in this study if you want to. But you don't have to be in it if you don't want to. Nobody will get mad at you if you don't want to do this.

If you decide to be in the study now and you change your mind later, that's okay, too. You just have to tell the study doctor or the study staff as soon as you change your mind, and you will be taken out of the study.

If you don't want to be in this study, just say so, and don't sign this form.

If you want to be in this study, please sign your name below.

If you sign here, it means you agree to participate in this study.

The doctor will give you a copy of this form to keep.

Adolescent's Signature

Date

Age

Adolescent's Name (*Print*)

Signature of Person Conducting Assent Discussion

Date

Signature of Person Conducting Assent Discussion (*Print*)