

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Efficacy of the Various Devices on Pupillary Dilation in Clinic and Intraocular Pressure Reduction in Patients with Glaucoma

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This is a clinical research study. Your study doctor, Julius Oatts, M.D. from the UCSF Department of Ophthalmology, will explain the study to you and your child.

Research studies include only people who choose to take part. Please take your time to make your decision about your child's participation. You may discuss your decision with your family and friends and with your child's health care team. If your child has any questions, he/she can ask the study doctor.

Your child is being asked to take part in this study because your child is being seen in our clinic for a dilated eye examination for the dilation arm of the study and receives routine eye care at UCSF.

Why is this study being done?

The proposed study looks to show MydCombi, a spray formulation for pupil dilation, that has similar or greater effect to dilation compared with standard of care eye drops.

How many people will take part in this study?

About 50 children and adolescents (2 to 17 years old) and 50 adults (18+ years old) will be in this study from UCSF.

What will happen if my child takes part in this research study?

If your child is taking part in the dilation arm, one of your child's eyes will be dilated with standard eye drops and the other eye will be dilated with the same medications with a MydCombi, decreasing the size of the eye drops. The study doctor will then measure each eye's pupil dilation (how wide pupils are) and cycloplegia (paralyzing eye muscles used to focus vision) 30 minutes after dilation.

How long will my child be in the study?

For the dilation arm, the study concludes at the end of the visit where your child's eyes are dilated.

Can my child stop being in the study?

Yes. You and your child can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop.

The study doctor may stop your child from taking part in this study at any time if he/she believes it is in your child's best interest or if the study is stopped.

What side effects or risks can I expect from my child's participation in the study?

Your child may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give your child medicines to help lessen side effects. Many side effects go away soon after your child stops the intervention. In some cases, side effects can be serious, long-lasting, or may never go away.

You should talk to your study doctor about any side effects your child experiences while taking part in the study.

Are there benefits to taking part in the study?

There will be no direct benefit to your child from participating in this study. However, this study will help doctors learn if MydCombi could be a possible alternative for providing dilation eye drop medications.

What other choices do I have if my child does not take part in this study?

Your child's other choices may include:

- Undergoing your child's scheduled visit without agreeing to participate in this study. Please talk to your doctor before deciding if your child will take part in this study.

How will my child's information be used?

Researchers will use your child's information to conduct this study. Once the study is done using your child's information, we may share them with other researchers so they can use them for other studies in the future. We will not share your child's name or any other personal information that would let the researchers know who your child are. We will not ask your child for additional permission to share this de-identified information.

Research results: There may be times when researchers using your child's information may learn new information. The researchers may or may not share these results with you and your child, depending on a number of factors.

How will information about my child be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that information about your child is kept confidential, but we cannot guarantee total privacy. Some information from your child's medical records will be collected and used for this study. If your child does not have a UCSF medical record, one will be created for him/her. Your signed consent form and some of your research tests will be added to your child's UCSF medical record.

Therefore, people involved with your child's future care and insurance may become aware of your participation and of any information added to your medical record as a result of your child's participation. Study tests that are performed by research labs, and information gathered directly from your child by the researchers will be part of your child's research records but will not be added to your child's medical record. Your child's personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your child's name and other personal information will not be used.

Authorized representatives from the University of California may review your child's research data for the purpose of monitoring or managing the conduct of this study.

Are there any costs to my child's participation in this study?

Two types of procedures will be done during this study. Some are part of your child's standard medical care and others are only for research. Your child or your child's insurer will be billed for the standard medical care. This includes the standard dilation in one eye. You will be responsible for your co-pays, deductibles, and any other charges that your child's insurer will not pay. There is a possibility that your child's insurer may not cover all standard medical care costs if your child is receiving medical services out of network. Any procedures done only for research will not be charged to your child or your child's insurer. This includes the use of the MydCombi device.

If you have questions about what costs you will be responsible for, please talk with the study investigator before deciding to enroll in the study. Depending on the type of study, some of your child's costs could be substantial.

Will I be paid for taking part in this study?

You will not be paid for taking part in this study.

What happens if my child is injured because he/she took part in this study?

It is important that you tell your child's study doctor, Dr. Julius Oatts, if you feel that your child has been injured because of taking part in this study. You can tell the doctor in person or call him/her at 415.353.2800.

Treatment and Compensation for Injury: If your child is injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to your child or your child's insurer just like any other medical costs or

covered by the University of California depending on a number of factors. The University and

the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

What are my rights if my child takes part in this study?

Taking part in this study is your and your child's choice. You may choose either to take part or not to take part in the study. If you and your child decide to take part in this study, you and your child may leave the study at any time. No matter what decision you and your child make, there will be no penalty to you or your child and he/she will not lose any of your regular benefits. Leaving the study will not affect your child's medical care. Your child can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your child's health or your willingness to continue in the study.

In the case of injury resulting from this study, you and your child do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your child's study doctor about any questions, concerns, or complaints you have about this study. Contact your child's study doctor, Dr. Julius Oatts at 415.353.2800.

If you wish to ask questions about the study or your child's rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the office of the Institutional Review Board at 415-476-1814.

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

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about your child.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

The person being considered for this study is unable to consent for himself/herself because he/she is a minor. By signing below, you are giving your permission for your child to be included in this study.

Date

Participant's Signature for Consent

Date

Person Obtaining Consent