Efficacy of the Nanodropper Device on Pupillary Dilation

NCT05274321

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

Study Title: Efficacy of the Nanodropper Device on Pupillary Dilation in Clinic and Intraocular Pressure Reduction in Patients with Glaucoma. (Nanodropper trial)

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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 or has stable glaucoma or ocular hypertension and receives routine eye care done at UCSF.

Why is this study being done?
The proposed study looks to show Nanodropper, an eye dropper adapter that creates smaller eye drops, has similar or greater effect to lower intraocular pressure (eye pressure) and dilation compared with standard of care eye drops.

How many people will take part in this study?
About 24 children and adolescents (0 to 17 years old) will be in this study from UCSF.

What will happen if my child takes part in this research study?
If you are 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 Nanodropper, 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.

If you are taking part in the glaucoma arm, Your child will be assigned to one of two groups:

a. Nanodropper for first 6 months, standard of care eye drops for last 6 months
b. Standard of care eye drops for first 6 months, Nanodropper for last 6 months

The study doctor will measure the intraocular pressure of your child each visit using an instrument called Goldman applanation tonometer. A small probe will lightly contact your child's eye.

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. For the glaucoma arm, your child will be in the study for five visits across a year span. Follow up visits will occur every 3 months. Each visit will consist of an IOP measurement.

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 you 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 you stop taking the measurement. In some cases, side effects can be serious, long-lasting, or may never go away. Below are specific risks within the study.

- *Applanation Tonometry (IOP Measurement Risks:* Because this test require eye drops and a probe to make brief contact with your child's eye, there are some risks including:
    - Eye irritation
    - Redness of eye
    - Discomfort
    - Tearing
    - small risk of corneal abrasion (scratch of the front eye), which usually heals on its own within a few days.

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 you from participating in this study. However, this study will help doctors learn if Nanodropper could be a possible solution for improving access to medication as well as decreasing healthcare costs.

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

- Undergoing your scheduled visit without agreeing to participate in this study. Please talk to your doctor before deciding if you 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 you are. We will not ask you 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, 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?
No. UCSF will pay for all items associated with this research study; you or your insurer will not be billed.

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 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 you or your 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 decide to take part in this study, you may leave the study at any time. No matter what decision you 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 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 study doctor about any questions, concerns, or complaints you have about this study. Contact your 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.

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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
Date	Witness – Only required if the participant is a non-English speaker