University of California, Los Angeles

CONSENT TO PARTICIPATE IN RESEARCH

Treatment of Ocular Discomfort in Glaucoma Patients Using Multiple Topical Medications

Dr. Benjamin Bert and Dr. Brian Francis from the Department of Ophthalmology at the University of California, Los Angeles (UCLA) are conducting a research study. This study is being funded by Novartis.

You were selected as a possible participant in this study because you have glaucoma and are using one or more topical glaucoma medications and have symptoms of ocular surface irritation (dry eye). In addition, have been prescribed the FDA-Approved medication Xiidra as part of your standard treatment. Your participation in this research study is voluntary.

Why is this study being done?
To evaluate glaucoma patients' response to treatment with Xiidra, an FDA-approved drug for ocular surface discomfort, which you have been prescribed as your standard of care treatment.

What will happen if I take part in this research study?
If you volunteer to participate in this study, the researcher will ask you to do the following at your routine clinic visits scheduled (at time of starting Xiidra, 2 weeks, 6 weeks, and 12 weeks):

- Undergo corneal fluorescein staining. This is a test that uses orange dye (fluorescein) and a blue light to detect foreign bodies in the eye. This test can also detect damage to the cornea, the outer surface of the eye.
- We will ask you questions regarding your eye discomfort
- We will review information from your Standard of Care Eye Exam in your medical records.

How long will I be in the research study?
Participation will last for 12 weeks. You will be asked to complete the above procedures at your routine clinical appointments at time of starting Xiidra 2, weeks, 6 weeks and 12 weeks. The additional time will be approximately 30 minutes at each visit.

Are there any potential risks or discomforts that I can expect from this study?
You may feel a slight stinging sensation when the dye for the corneal staining is first applied. After a few moments, the dye will feel like normal liquid on the eye and will no longer be uncomfortable. Your eye surface may have a light-yellow appearance temporarily.

The risks associated with the use of the Fluorescein eye drops are of minor allergic reactions with redness and burning sensation. There is a very rare risk of a severe allergic reaction that could damage the cornea

You may become tired from the additional questionnaires. You may skip any questions that make you feel uncomfortable.

Are there any potential benefits if I participate?
You are not expected to directly benefit from your participation on this study.

The results of the research may valuable data on the benefits of Xiidra for patients with glaucoma and may assist with the treatment of future patients.

What other choices do I have if I choose not to participate?
You may continue to take the medication and not participate in the study as it is an approved medication for this condition.

Will I be paid for my participation?
You will not be paid for your participation in this research study. However, you will be provided with a parking voucher for each of the four study visits.

Will information about me and my participation be kept confidential?
The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security. Confidentiality will be maintained by means of assigning a numeric code when you are enrolled. All data will be collected and stored under this code.

The research team, authorized UCLA personnel, the study sponsor, and regulatory agencies such as the Food and Drug Administration (FDA), may have access to study data and records to monitor the study. Research records provided to authorized, non-UCLA personnel will not contain identifiable information about you. Publications and/or presentations that result from this study will not identify you by name.

Public Information about this Study:
ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."

What are my rights if I take part in this study?
- You can choose whether or not you want to be in this study, and you may withdraw your consent and discontinue participation at any time.
- Whatever decision you make, there will be no penalty to you, and no loss of benefits to which you were otherwise entitled.
- You may refuse to answer any questions that you do not want to answer and still remain in the study.

Who can I contact if I have questions about this study?
- **The research team:**

If you have any questions, comments or concerns about the research, you can talk to the one of the researchers. Please contact:

Benjamin Bert, MD 714-963-1444

- **UCLA Office of the Human Research Protection Program (OHRPP):** If you have questions about your rights as a research subject, or you have concerns or suggestions and you want to talk to someone other than the researchers, you may contact the UCLA OHRPP by phone: (310) 206-2040; by email: participants@research.ucla.edu or by mail: Box 951406, Los Angeles, CA 90095-1406.

You will be given a copy of this information to keep for your records.

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

SIGNATURE OF STUDY PARTICIPANT

Name of Participant	
Signature of Participant	Date

SIGNATURE OF PERSON OBTAINING CONSENT

Name of Person Obtaining Consent	Contact Number
Signature of Person Obtaining Consent	Date