ForPatients
by Roche

Dry eye syndrome

A biomarker study to characterize response to anti-inflammatory treatment for dry eye disease

A Study to Explore Signs, Symptoms, and Biomarkers in Dry Eye Disease Participants Following Anti-inflammatory Treatment

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Countries	NCT07025811 BP45931

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This study aims to evaluate the performance of biomarkers and their responsiveness to standard-of-care treatments (Vevye® or Xiidra®), in participants with dry eye disease (DED) compared to healthy volunteers (control participants).

Hoffmann-La Roche Sponsor	**Phase 4** Phase

NCT07025811 BP45931
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	Accepts Healthy Volunteers

1. Why is this study needed?

Dry eye disease (DED) is a condition where eyes do not stay properly hydrated, leading to discomfort and vision problems. While there are FDA-approved treatments available, we still need to better understand how these treatments work and what makes healthy eyes different from eyes affected by DED.

This study is examining two FDA#approved medications: Vevye ® (cyclosporine ophthalmic solution) and Xiidra ® (lifitegrast ophthalmic solution), which are used to treat DED. By comparing people receiving these treatments with healthy volunteers over time, we can better understand how these treatments affect the eyes, identify differences

between healthy eyes and those with DED, and study various biological markers, which are indicators in the body, that could help improve DED diagnosis and treatment.

This research is needed because it will help develop more effective ways to diagnose and treat DED in the future.

2. Who can take part in the study?

To participate, individuals must meet all the requirements determined by the study team.

Healthy people (males or females) of 18 years of age or older can take part in the study as a healthy volunteer.

People (males or females) of 18 years of age or older with DED can take part in the study if they:

- Are currently using or have wanted to use artificial tears
- Have specific symptoms of eye dryness that the study doctor will measure
- Have adequate vision
- Need prescription medication to treat DED, as determined by the study doctor

People with DED may not be able to take part in this study if they:

- Have high eye pressure,
- Have had certain eye problems or infections in the last 3 months
- Have had eye surgery in the past year
- Have used specific glaucoma or DED treatments in the last 6 months
- Have had recent procedures for eyelid gland issues,
- Currently wear contact lenses
- Have smoked in the last 3 months
- Have been in another clinical trial recently

Healthy people or people with DED who are pregnant, or currently breastfeeding cannot take part in the study.

3. How does this study work?

People will be screened to check if they are able to participate in the study. The screening period will take place from up to 19 days before the start of the study.

For people with DED, everyone who joins this study will be split into 2 groups randomly (like flipping a coin) and given either Vevye, given as one drop into the affected eye(s) twice daily OR Xiidra, given as one drop into the affected eye(s) twice daily. Participants will have an equal chance of being placed in either group. Participants will know which

treatment they receive but the study doctor will not. However, the study doctor can access this information if needed.

Healthy people who join this study will not receive any study treatment.

During this study, the study doctor will see participants four times to perform assessments and to collect samples for the study. Participants will receive telephone calls from the study doctor twice during the study to remind them to complete questionnaires at home. Total time of participation in the study will be about 3.5 months. Participants have the right to stop study treatment and leave the study at any time, if they wish to do so.

4. What are the main results measured in this study?

The main results measured in the study are changes in the eye, as well as DED-related symptoms from the start of the study to 12 weeks. This includes measuring the condition of the eye surface (including the conjunctiva–the outer layer that covers the white of the eye), the amount of tears produced, and how participants feel about their eye comfort. Other key results include analyzing samples from the eye surface to understand the biological differences between healthy eyes and those with DED, and how treatments might be working.

5. Are there any risks or benefits in taking part in this study?

Taking part in the study may or may not make participants feel better. But the information collected in the study can help other people with similar health conditions in the future.

Participants may have unwanted effects of the drugs, or procedures used in this study. Talk to your study doctor right away if any unwanted effects happen during the study. During this study, participants will have regular check-ups to see if there are any unwanted effects.

Both treatments (Vevye and Xiidra) used in this study are approved medicines for the treatment of DED and have been shown to be safe in clinical studies. Vevye and Xiidra will be given as eye drops. Known unwanted effects include eye discomfort, temporary blurry vision, and taste changes.

This study includes several eye examinations and tests. One of these involves collecting cell samples from the white part of your eye using a special device called EyePrim™. This device works like a gentle stamp that briefly touches your eye surface for 2-3 seconds to collect cells for research. While this procedure is safe, you might experience: temporary eye irritation, redness of the eye, and/or mild discomfort. These effects typically last from a few hours to a few days and resolve on their own. The eye surface heals completely within 24 hours.

Full details about all procedures and their risks are provided in the Informed Consent Form.

The study involves some risks to the participant. But these risks are generally not greater than those related to routine medical care or the natural progression of the health condition. People interested in taking part will be informed about the risks and benefits, as well as any additional procedures or tests they may need to undergo. All details of the study will be described in an informed consent document. This includes information about possible effects and other options of treatment.