

Study Comparing Eye Drops for Dry Eye Condition in People with Autoimmune Diseases

Official Trial Name

A Multicenter, Randomized, Controlled, Double-Masked, Phase 2 Trial of the Safety and Therapeutic Effects of X-1 Versus Vehicle Control for Treatment of Dry-Eye Disease in Patients with Autoimmune Disease

What the Study is About

Currently, eye inflammation diseases are treated with steroids, immune system suppressors, and antibiotics. However, these treatments are not always effective and can be unsafe for long-term use. Therefore, new treatments are needed, preferably ones that can be applied directly to the eye to avoid potential whole-body side effects.



What the Study is Measuring

We aim to understand whether different doses of X-1 can reduce ocular inflammation and improve symptoms, and whether the treatment is safe for patients.

Main Goal

The primary goal of this study is to determine the safety and efficacy of X-1 in treating inflammatory ocular diseases.

Other Goals

The results of this trial could potentially lead to a new treatment option for patients with inflammatory ocular diseases.



Who Can Participate

Age Range

18 to 85 years

Biological Sexes

Males and Females

Condition Being Studied

They must have a diagnosis of DED or ocular inflammation

Other Key Criteria

- Have dry eye disease (DED) and ocular inflammation
- Must have an autoimmune disease, such as Sjogren's disease, lupus, chronic osteoarthritis, atopic dermatitis, rheumatoid arthritis, ankylosing spondylitis, scleroderma, Hashimoto's thyroiditis, Crohn's disease
- Be able and willing to use the study's eye drops



How the Study is Designed

This is a randomized controlled trial involving three arms
In Arm 1, participants will receive a low-dose (0.1%) eye drops.

In Arm 2, participants will receive a high-dose (0.3%) eye drops.

In Arm 3, participants will receive a placebo controlled comparator



Risks and Benefits

While participating in a clinical trial can provide access to new and potentially more effective treatments, it also involves certain risks and uncertainties. It's important for potential participants to weigh these factors and discuss them with their healthcare providers before deciding to join a trial.

Risks

- Increased eye pressure: The eye drops might cause the pressure inside your eyes to rise.
- Irritation or discomfort: The eye drops could make existing eye surface issues worse, leading to more dryness or irritation
- Allergic reactions: There's a chance that some people might be allergic or overly sensitive to the eye drops.

Benefits

- Potential for participants to improve symptoms without resorting to surgery.
- May reduce eye inflammation and minimize safety concerns.



How the Study is Funded

This study is sponsored by a Principal Investigator from a leading university, a leader in academic research and medical innovation. The university's involvement guarantees high scientific standards and boosts the study's credibility. With its strong reputation and commitment to advancing knowledge, Their sponsorship ensures the study is conducted with integrity and potential for significant impact in ophthalmology.