



Study Sponsored by Dompé farmaceutici S.p.A.

Hello,

We are pleased to share information about a new clinical research study already enrolling in your area for individuals with Sjögren's Dry Eye. Your participation in this study could help patients worldwide and I hope you will consider learning more. The purpose of this study is to investigate the safety and efficacy of Oxervate® in patients with Sjögren's Dry Eye Disease.

This new investigational study, NGF0221, is looking for individuals diagnosed with Sjögren's, or other associated autoimmune conditions known to induce dry eye disease. Inclusion criteria include:

- Participants can be male or female ages 18 and older
- Participants with dry eye-related symptoms
- Participants should be under treatment with topical cyclosporine, or topical ophthalmic treatments of the same class for at least 30 days before screening and will continue the use of topical cyclosporine, or topical ophthalmic treatments during the study
- The use of topical corticosteroids, lifitegrast, or autologous serum tears will not be allowed upon enrolling into and during the study's treatment period.

If you are enrolled in this study, you will participate for approximately 25 weeks. Your participation will include an initial screening visit, followed by 7 more visits to our study center. You will be reimbursed for your time. Your participation in this study is strictly voluntary, meaning that you may or may not choose to take part. Choosing not to participate in the study or leaving the study after you join will not result in any penalty or loss of benefits to which you are otherwise entitled.

For more information and to see if you may be eligible to participate, please contact:

Dr. Melissa Morrison Toyos
Toyos Clinic
2204 Crestmoor Road
Nashville, TN 37215

To learn more call Sarah Smith, Clinical Trial Coordinator at (615) 327-4015 ext. 0 or email ssmith@toyosclinic.com

On behalf of the millions of Sjögren's sufferers in this country, I thank you for taking time to learn more about this study.

Oxervate® is FDA approved for Neurotrophic Keratitis. Oxervate is not FDA approved for Sjögren's Dry Eye Disease and is currently being investigated under clinical trials.

Sincerely,

A handwritten signature in black ink that reads "Sherise DeAngelis".

Sjögren's Foundation VP of Corporate Relations

Note: You received this notice because of your participation and/or interest in the Sjögren's Foundation. The Foundation sends this research notice for information only. It does not represent an endorsement of this study but only makes you aware of this research project for your participation if you choose.