

The K-321-301 Study

A clinical study for patients with Fuchs Endothelial Corneal Dystrophy

As someone living with Fuchs Endothelial Corneal Dystrophy (FECD), you may be interested in learning about the **K-321-301 Study**, a clinical trial investigating a new therapy designed to help treat FECD.

What is the purpose of the study?

Researchers are looking for better ways to correct visual difficulties of patients living with FECD. Current treatments for FECD include a procedure known as Descemet Stripping Only (DSO), during which the damaged tissue is stripped away. Once the diseased area is removed from the cornea, the patient's own healthy cells move from the outer edges of the cornea to the center. A new investigational medicine called ripasudil (K-321) may help speed up healing and recovery of vision after DSO compared to DSO alone.

What happens during the study?

This study lasts about a year and has four parts: screening, DSO, treatment, and follow-up. There are 15 study visits in total.

Screening	Descemet Stripping Only (DSO) procedure	Treatment	Follow-up
Up to 4 weeks before			
start of treatment	Day -1	12 weeks	40 weeks
1 visit	1 visit	8 visits	5 visits

What is the treatment?

The drug being studied is ripasudil ophthalmic solution 0.4% (K-321). It is administered as an eye drop. In several studies, K-321 has been found to help wounds heal faster and improve vision in FECD patients undergoing DSO alone.

Patients will be randomly assigned to one of these treatment groups:

K-321 - 4 times daily

Placebo (no active ingredient)—4 times daily

Neither you nor the study doctor will know which study drug you are using. If you would like to learn more about the K-321-301 Study, please contact:

Site	Location	Physician	Contact Phone Number	Study Coordinator	Study Coordinator Phone Number
Verdier Eye Center	Grand Rapids, Michigan	David Verdier	(616) 949-2001	Devon Keeler	(616) 949-2001 x1111
Keck Hospital of USC	Los Angeles, California	Jun-Min Martin Heur	(800) 872-2273	Yuping Wang	(626) 615-9618
Precision Cornea Centre	Ottawa	Kashif Baig	(613) 746-2244	Andrew Samuel	(613) 746-2244 xExt408
Dr. Greg Moloney	Vancouver, British Columbia	Gregory Moloney	N/A	Yumi Ohashi	(604) 875-8889
Prism Eye Institute - Mississauga-Oakville	Oakville, Ontario	Joshua Teichman	(905) 820-3937	Zhang Richard	(905) 456-3937 xext267
Bascom Palmer Eye Institute	Palm Beach Gardens, Florida	Ellen Koo	N/A	Olufemi Sangoyomi	(561) 515-1549
Macy Eye Center	Los Angeles, California	Jonathan Macy	(310) 657-2777	Andrea Veneziano	(310) 657-2777
Bascom Palmer Eye Institute - Naples	Naples, Florida	Jaime Martinez Martinez	N/A	Yasniel Gonzalez	(239) 659-3962
Houston Eye Associates	Houston, Texas	John Goosey	(713) 558-8777	Marcel Belloso	(713) 668-6828 x2624
University of Wisconsin - 2870 University Av	Madison, Wisconsin	Evan Warner	(608) 262-2515	Angie Adler	(608) 265-7557
R and R Eye Research, LLC.	San Antonio, Texas	Gregory Brunin	(210) 340-1212	Catherine Hazen	(210) 340-1212
Vance Thompson Vision West Fargo	West Fargo, North Dakota	Michael Greenwood	(701) 566-5390	Alyson Saville	(701) 809-9905
Vance Thompson Vision - Omaha	Omaha, Nebraska	Brandon Baartman	(402) 347-4680	Sarah Hartnett	(402) 899-8020
Casey Eye Institute - OHSU	Portland	Winston Chamberlain	(503) 494-7674	Kenia Chavez	(503) 494-1986
University Hospitals Cleveland Medical Cent	Cleveland, Ohio	Ahmed Farghaly Abdelhameed	(216) 844-3601	Sangeetha Raghupathy	(216) 844-8552
Gorovoy MD Eye Specialists	Fort Myers, Florida	Mark Gorovoy	(239) 939-1444	Carrie Soto	(239) 939-1444
W Kellogg Eye Center	Ann Arbor, Michigan	Shahzad Mian	(734) 763-8122	Kristin Jones	(734) 615-4290
Eye Associates of New Mexico	Albuquerque, New Mexico	Kenneth Himmel	(505) 888-5757	Martha Conklin	(505) 393-7483
Byers Eye Institute at Stanford	Palo Alto, California	Charles Lin	(650) 497-7935	Zac Wennberg-Smith	(650) 497-5942
Devers Eye Institute	Portland, Oregon	Michael Straiko	(503) 413-8032	Alex Bauer	(503) 413-8032
University of Texas Southwestern Medical C	Dallas, Texas	Venkateswara Vinod Mootha	(214) 648-3111	Daphne Fuerte	(214) 645-2012
Sacramento Eye Consultants	Sacramento, California	Patricia Sierra	(916) 649-1515	Madelyn Pownceby	(916) 649-1515 xext250