

## ABOUT RESEARCH STUDY

Pharmaceutical companies use research studies like the GLK-601-01 (AMB-01-006) study to learn more about investigational drugs before they are made available to the public. The results of this study will provide more information about the investigational drug being evaluated in this study. By taking part in the GLK-601-01 study, you will be making an important contribution to PCED treatment research.



TO LEARN MORE ABOUT THE GLK-601-01  
(AMB-01-006 ) STUDY, PLEASE CONTACT:

<INSERT TEXT>

GLAUKOS<sup>®</sup>  
TRANSFORMING VISION

**DON'T LET  
PCED KEEP  
YOU FROM  
WHAT YOU  
LOVE**



There is an ongoing research study for those that have experienced persistent corneal epithelial defects (PCED).

Learn how you could participate.

# YOU HAVE BEEN DIAGNOSED WITH PERSISTENT CORNEAL EPITHELIAL DEFECT

A healthy corneal epithelium is essential for protecting the eye against infection and structural damage to deeper tissues. Corneal epithelial defects, a focal area of epithelial (outermost corneal layer) loss; can be due to mechanical trauma, corneal dryness, neurotrophic cornea, post-surgical changes or any other variety of etiologies. Corneal epithelial defects are one of the most commonly seen ocular pathologies in the general patient population.

Treatment of a persistent corneal epithelial defect is based upon the clinical condition of the epithelium at presentation as well as the underlying etiology. For example, the PCED from band keratopathy is managed by treating the underlying band keratopathy with EDTA chelation.

Your study doctor and their colleagues are conducting a research study with Glaukos Corporation (Glaukos). This study will investigate how safe and how effective or well the investigational drug, NEXAGON, is for healing wounds on the surface of the eye. Your study doctor will also continue to treat your eye with other standard eye medicines whilst you are participating in the study, which means you will still receive your usual medical care. NEXAGON, the study drug, is investigational because it has not been approved for use by the U.S. Food and Drug Administration (FDA) or other similar authorities in other countries.

You are being offered the opportunity to participate in this study because you have a PCED that is not due to an active infectious etiology. The PCED has been present for at least 2 weeks and has not healed as your doctor would expect, despite treating you with the best available medicines and procedures.

## WHO IS ELIGIBLE TO PARTICIPATE IN THE PCED STUDY?

To pre-qualify for this study, you must have:

- Diagnosis of non-infected PCED in one or both eyes
- PCED non-responsive to current standard of care
- Be at least 2 years old

All study-related visits, tests, and medications will be provided at no cost. In addition, reimbursement for study-related travel may be provided.

## WHAT WILL HAPPEN DURING THE PCED STUDY?

If you wish to take part in this study, you will be asked by your study doctor to sign a consent form. This form shows your agreement to take part in the study, and you will be given a copy to take home with you. The study doctor will ask you a number of general questions, including your age, ethnicity, medical history, eye examination and PCED history including the cause of your defect, assessment of your defect, and any medications or procedures you have had since your defect, and medications you are currently using.

Once your study doctor has confirmed that you are still eligible to continue on Day 1 of the study Treatment Period, you will be randomly assigned (by chance – like the toss of a coin) to one of the study treatments. This will be either NEXAGON 0.06% or a Placebo (a dummy, inactive treatment, also known as Vehicle, that does not contain any drug but looks and feels the same).

## WHAT ARE THE BENEFITS AND RISKS RELATED TO THE PCED STUDY?

You may not benefit from taking part in this study.

The eye medicines that your doctor or doctors have been prescribing for you are the current standard of care for your condition but have not been working to resolve your PCED.

The benefit to you, if you are deemed eligible, would be the use of a treatment that has been shown to be effective in some patients with a similar condition to yours that have been treated with NEXAGON. The study treatment you receive may help your PCED to heal during the course of the study. However, this cannot be guaranteed.

# THERE IS AN ONGOING PERSISTENT CORNEAL EPITHELIAL DEFECT (PCED) CLINICAL TRIAL IN YOUR AREA!

If you have a patient with a PCED non-responsive to standard of care, **please contact the site below** to refer your patient for this important clinical research.

SCAN FOR MORE INFORMATION



SITE NAME

SITE ADDRESS LINE 1

SITE ADDRESS LINE 2

PHONE NUMBER

In the spirit of good collaboration, **your patient will be encouraged to continue under your care** - with the exception of their participation in the PCED study.

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## **HAVE YOU BEEN DIAGNOSED WITH PERSISTENT CORNEAL EPITHELIAL DEFECTS?**

**We are currently conducting a study for people who have been diagnosed  
with Persistent Corneal Epithelial Defects**

**You may be a possible candidate for this study  
if you meet the following criteria:**

- Male or female, 2 years of age or older
- Have a diagnosis of Persistent Corneal Epithelial Defects
- Able to be seen once weekly for up to 8 weeks  
with a follow-up period of 4 weeks
- Do not have an eye disease requiring drops in the eye

**The objective of this study is to evaluate the safety and  
efficacy of a new investigational research compound in  
subjects with Persistent Corneal Epithelial Defects  
(NEXPEDE-1)**

**The expected study duration is approximately 56 to 91 days  
(with a possibility of an additional 90 days)**

If you would like more information regarding this  
study, please contact our research department

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