



For assistance scheduling a patient at a study site:

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### **RATIONALE:**

The role of steroids in acanthamoeba is unclear. In the lab, steroids promote growth of acanthamoeba. But steroids may also help with pain and could improve vision by reducing scarring. Ophthalmologists disagree on the best approach, and there is very little evidence to guide treatment decisions.

### **STUDY DETAILS:**

**Design:** Randomized clinical trial assessing the safety and efficacy of topical steroids for acanthamoeba keratitis.

#### **Inclusion criteria:**

- Acanthamoeba keratitis on culture / smear / PCR / confocal
- Ocular inflammation after 4 weeks of PHMB therapy
- Age  $\geq$  8 years

#### **Main exclusion criteria:**

- Herpetic or fungal keratitis
- No Light Perception in affected eye
- Corneal perforation
- Concurrent treatment with oral steroids

**Intervention:** Patients randomized to topical dexamethasone 0.1% or an artificial tear after 4 weeks of PHMB. (Late enough that PHMB can kill the acanthamoeba; soon enough that the steroids may help reduce scarring.)

**Primary outcome:** Best corrected visual acuity at 6 months

**Study visits:** week 4, week 6, months 2, 4, 6, and 12

**Sponsor / Funder:** Proctor Foundation (UCSF) / National Eye Institute

### **PUTT STUDY SITES:**

#### **USA:**

- Columbia University (Harkness)
- Johns Hopkins University (Wilmer)
- University of California, Los Angeles (Stein)
- University of California, San Francisco / Proctor
- University of Florida, Gainesville
- University of Illinois at Chicago
- University of Iowa
- University of Miami (Bascom Palmer)
- University of Michigan (Kellogg)
- University of Pennsylvania (Scheie)
- University of Pittsburgh
- Oregon Health and Science University

#### **UK:**

- Moorfields Eye Hospital

#### **India:**

- Aravind Eye Hospital - Coimbatore
- Aravind Eye Hospital - Madurai

#### **Brazil:**

- Universidade Federal de São Paulo

### **WHY PARTICIPATE?**

- The research study will pay for PHMB for the duration of the study. The PHMB is manufactured by an Italian pharmaceutical company to high standards using a high-quality drug product. This formulation of PHMB was 88% effective in the recent ODAK trial from Moorfields, and not yet available in the USA.
- Close monitoring by experts in acanthamoeba keratitis.
- Help others with acanthamoeba! We truly do not know the place of steroids in this disease, and a trial will be helpful to future patients with this infection.

### **HOW TO HELP:**

Consider acanthamoeba: Remember the early signs of acanthamoeba keratitis in all contact lens wearers: diffuse or pseudoendritic epitheliopathy, radial perineuritis, patchy anterior stromal scars with or without an epithelial defect. Late signs include ring ulcers and scleritis.

Refer: If you are suspicious of acanthamoeba keratitis or get a positive result on culture / smear / PCR, send the patient to one of the PUTT centers (see list above).