



Parasitic Ulcer Treatment Trial

What is the trial about?

- Acanthamoeba corneal infections are challenging to treat. Patients often need eyedrops for the infection for 6 to 12 months or even longer.
- Doctors don't know the best way to treat acanthamoeba. Some doctors think steroid drops help with vision and pain, but other doctors think steroids prolong the infection.
- In this research study, everyone will be treated with an eyedrop for acanthamoeba for the duration of the infection. After 1 month, some people will be started on steroid eyedrops and other people will get lubricating eyedrops. We will follow everyone closely to see if steroids are safe and effective for acanthamoeba infections.

What is involved?

- You will be treated with an eyedrop for acanthamoeba for 1 month.
- After 1 month, if you are still eligible, you will be "randomized" to get either the steroid eyedrop or a lubricating eyedrop. (Randomization is similar to flipping a coin.) You will not know which treatment you get.
- You will take the study eyedrop for 2 months while you are still taking the anti-amoebic eyedrop.
- You will have follow-up visits at the 1-month visit, and also at 6 weeks, 2 months, 3 months, 6 months, and 12 months. (You will also have other visits for your clinical care as recommended by your doctor.) You can expect each visit to last about 2 hours.
- You will have several different types of eye images taken throughout the study, as well as a very precise test of your vision.

Why should I participate?

- The study will pay for your anti-amoeba medication. (Insurance usually doesn't pay.)
- Medications for acanthamoeba eye infections are not available from your local pharmacy in the USA. Instead, doctors have to order eyedrops from a compounding pharmacy. However, in this study you will be treated with a new eyedrop made in a dedicated facility by a European pharmaceutical company. This eyedrop was found to be very effective for acanthamoeba eye infections. It recently received approval in Europe but is not yet available in the USA. You will get access to this effective medication as part of this trial.
- Your doctor will be monitoring you very closely with some tests that would not be done outside the study. This close monitoring may give your doctor more information to help them treat your eye infection better. Only doctors with significant experience treating corneal ulcers were invited to participate in this study.
- Help others! The results of this study will allow doctors to treat acanthamoeba in the best way possible, helping people who may be infected in the future.
- Participation is voluntary. You can still get care if you don't participate. You can stop participating in the study at any point.

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