

At the five study visits, a variety of specialist medical tests will be carried out. These will include:

- eye examinations
- vision tests
- eye swabs
- questions about your medical history and any drugs that you are taking
- a urine pregnancy test (if you are a woman who is able to have children)

By taking part in this study, you will find out what type of pink eye you have (adenoviral or bacterial).

What else do I need to consider?

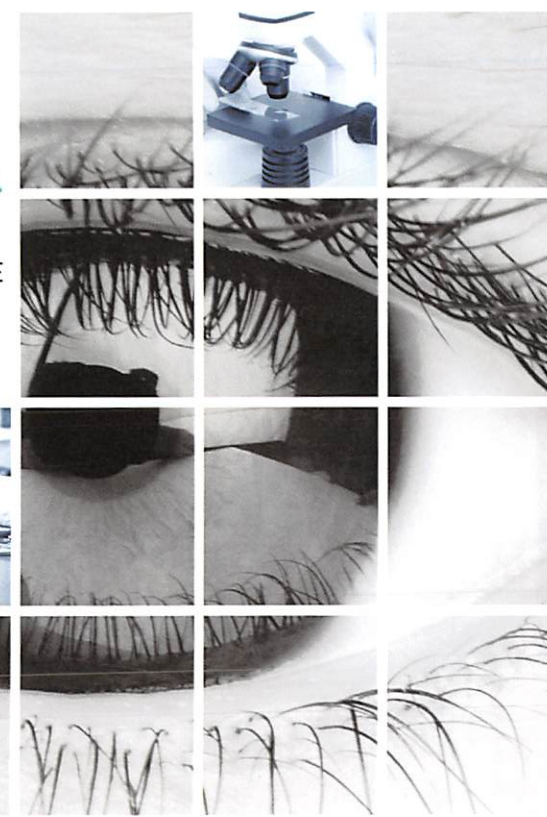
Your participation in this study is entirely voluntary. You can leave the study at any time, and will not need to give a reason. The study team will be able to explain the benefits and risks of taking part in the study. By taking part, you will help to increase our understanding of how pink eye could be treated.



What do I do now?

It is important that you contact the study team **within 3 days** of the **start** of your symptoms if you are interested in participating. If you are interested in learning more about the Synchronize 302 and Synchronize 303 research studies, please use the details provided below to contact the study team.

Eyeland Vision 915-821-6800
www.eyelandvision.com
4775 Loma del Sur
El Paso, TX 79934



Synchronize 302 and Synchronize 303 Patient Information

**Do you have redness, watering,
or irritation of the eye?**

**Do you think you might have
conjunctivitis, commonly
referred to as “pink eye”?**

The Synchronize research studies will look at a potential new drug for pink eye caused by adenoviruses or bacteria.

Contact us **within 3 days** of your symptoms starting to learn whether you could take part in a research study and receive specialist care from the study team.

What is a research study?

A research study (also known as a clinical trial) is a medical study that is designed to answer questions about the safety of potential new drugs and to find out how well they work. Research studies must be performed before a potential new drug can be approved for use in patients.

This brochure contains information that will help you to decide whether you (or your child) would like to participate in the Synchronize 302 or Synchronize 303 research studies, which involve testing a potential new drug for pink eye caused by adenoviruses or bacteria.

What is pink eye?

Pink eye is a temporary infection of the conjunctiva (the thin lining that covers the whites of the eyes and the insides of the eyelids). The infection is usually caused by adenoviruses (a type of virus) or bacteria. Pink eye can affect people of all ages. People with pink eye may have signs and symptoms such as redness, watering/discharge, irritation, or soreness of the eyes for a few days to a few weeks before their symptoms improve.

Pink eye caused by adenoviruses is most common in adults, but the bacterial form is more common in children. Doctors can tell the difference between adenoviral and bacterial pink eye by using a test that requires an eye swab. It usually takes approximately 10 minutes to tell you if your doctor whether the infection is caused by an adenovirus or bacteria.

How do people get pink eye?

Pink eye spreads very easily between people and from one eye to the other eye in the same person. The viruses or bacteria that cause pink eye are spread through contact between the hands or eye. If you have, or if someone who lives with you has, pink eye, then it is important to wash your hands often and to avoid touching your eyes.

How is pink eye usually treated?

Pink eye cannot always be treated with drugs. Pink eye usually gets better within a few days to a week. The symptoms can be very uncomfortable, but there is a high chance that the infection will go away on its own. Doctors may use various ways to help relieve the symptoms and discomfort, such as:

- avoiding contact lenses
- using lubricating eye drops (artificial tears) to reduce soreness and stickiness in the eyes
- applying a cold compress to relieve discomfort
- cleaning away sticky discharge using a cotton pad soaked in water
- using eye drops or ointments. There are no drugs available to treat pink eye caused by adenoviruses. For pink eye caused by bacteria, antibiotic eye drops or eye ointments may help clear up the infection more quickly and relieve symptoms.

Doctors do not use antibiotics when they are not necessary (e.g. to treat pink eye caused by adenoviruses), the greater the chance that the bacteria will become resistant to them, and then the antibiotics can no longer be used to treat these bacterial infections. Antibiotic resistance is a growing concern for patient safety worldwide, caused by overuse and inappropriate use of antibiotics.

New drugs that work for **both** adenoviral and bacterial causes of pink eye are needed to relieve symptoms, speed up recovery, and reduce unnecessary antibiotic use when the cause is an adenovirus.

What are the Synchronize 302 and Synchronize 303 research studies?

The Synchronize 302 and Synchronize 303 research studies are looking at a non-antibiotic potential new drug targeted for use with two of the most common forms of pink eye – those caused by adenoviruses or bacterial infection.

The non-antibiotic investigational drug is a combination of an antiseptic (which kills certain viruses and bacteria) and a steroid (which aims to reduce pink eye symptoms).

By taking part, you and/or your child may receive a potential new drug for pink eye, and all study-related procedures and visits, including care from an eye specialist, are provided at no cost.

We are looking for about 284 people with pink eye caused by an adenovirus to take part in the Synchronize 302 research study and about 721 people with pink eye caused by bacteria to take part in the Synchronize 303 research study.



Can I take part in the Synchronize 302 and Synchronize 303 research studies?

Both adults and children of any age may be able to take part in one of the Synchronize research studies. You (or your child) may be able to participate if you (or they):

- have had pink eye signs or symptoms (e.g. redness, watering/discharge, or irritation) in at least one eye for **no more than the past 3 days**
- are interested in taking part in a research study for up to 13 days
- are willing to travel to the study center for appointments

Additional criteria, including some for newborn infants and young babies, may apply.

Why is it important to include children in the Synchronize research studies?

Children are often affected by pink eye, and drugs do not always work in the same way for children as they do for adults. It is important that drugs that are intended for use in children have been used by children as part of a research study like this one.

Can other household members join the Synchronize research studies?

Pink eye infections can be passed between people who have close contact, so it is possible that several people in your household could be affected at the same time. If this happens, all household members who qualify may take part in one of the Synchronize research studies.

What will the Synchronize 302 and Synchronize 303 research studies involve?

The Synchronize 302 and Synchronize 303 research studies will involve five visits to the study center over a 13-day period.

