CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Comparison of Intracanalicular Dexamethasone Insert to Topical Loteprednol Etabonate Ophthalmic gel 0.38% in Patients with Keratoconus (KC) with Allergic Conjunctivitis and underlying Dry Eye Disease (DED)

DESCRIPTION

Keratoconus may cause your vision to be blurry with glasses alone. Often contact lenses are needed to improve vision. Patients with keratoconus may have dry eye and allergies. Dry eye can cause your eyes to feel as if they are gritty and may cause you to rub them more often than normal. Dry eye and allergies may be treated by putting topical steroid drops in your eyes several times a day. Treatment is important to prevent further damage to the eye which can cause your vision to be cloudy. Treatment may also make your contact lenses more comfortable. Some patients have difficulty putting in drops while wearing their contact lenses and some drops cause irritation to the eye. We want to know if one method of treatment (intracanalicular insert of dexamethasone) improves the signs and symptoms of ocular allergy and dry eye compared to the use of topical loteprednol etabonate ophthalmic gel 0.38%.

METHOD

You will be among 20 people selected for this study from the Illinois Eye Institute patient population. You must have a complete eye examination at the Illinois Eye Institute within the last year. You must have a problem with keratoconus and wear contact lenses. You must have dry eye and ocular allergies and we have to be able to tell that you have this by looking at your cornea. If you have had a history of elevated eye pressure with topical steroid use, you will not be eligible to participate in the study. You will have a total of five visits if you participate in this study.

If you have these problems, then we will need to take a few measurements to tell how dry your eyes are and put fluorescein dye in your eyes so that we can look at the front of your eye and record how it looks today. The dye will be placed on the white part of your eye. You should not feel the dye in your eye and it should not affect your vision. Also, you will be asked questions describing how dry your eyes feel today by the researcher and she will document your answers.

We will insert dexamethasone into one puncta (the drainage opening of your tears in your lower lid) of one eye. We will use an instrument to help widen the drainage opening of your tears in your lower lid. You may feel a little pressure while this is being done, but it will not hurt. We will use forceps to insert the medication into the drainage opening of your tears in your lower lid. If you begin to feel this, we will instill a numbing drop to make you more comfortable. The medication will stay in place for one month and the insert will dissolve within 60-90 days. You do not need to do anything additional

for this eye when you get home. If you feel slight discomfort, you may use preservative free artificial tears 4 times per day which will be provided to you.

You will be given loteprednol gel drops for the other eye. You will receive a free month's supply of loteprednol etabonate ophthalmic gel at the beginning of the study to use during the study. We will tell you which eye to use the drops. We ask that you put one drop in each eye four times per day for the first week. These drops will then be reduced as instructed by the investigator. You will be given 2 bottles of the loteprednol. At the end of the study, you will be asked to turn in your bottles. Steroid drops may cause an increase in eye pressure. To monitor this, your eye pressure will be measured at each visit by using a probe to gently touch the eye. A numbing drop will be used so that you do not feel this. Looking at the front of your eye, taking the measurements and explaining how to use the medication should take about 30 minutes.

We will then schedule an appointment for you to come back in one day, one week, one month and at 3 months so that we can discuss how your eyes are feeling, look at your cornea, and collect your calendar. This part should take about 30 minutes also.

BENEFITS

The study will help us understand which method of medication is preferred for patients with keratoconus with ocular allergy and dry eye.

RISKS

Sometimes, people are sensitive to the fluorescein dye and medications. When this happens, then the front of their eye can be damaged when fluorescein is put in their eye. Therefore, if you have ever had problems when the eye doctor has used fluorescein in your eye or have a sensitivity to any medication, then please tell us.

Also, when you put drops in your eyes, the bottle that the drops come in can become dirty, especially if you use older bottles of drops. Dirty bottles may cause an eye infection. If your bottle becomes dirty, stop using it and open a new bottle. You will be provided 2 bottles at the start of the study. Sometimes patients notice discomfort when having medications and/or instruments inserted into their puncta. If this happens, your eye may become red and itchy. A new medication and sterilized instrument will be used on each patient to prevent this.

Steroid drops may cause an increase in eye pressure. To monitor this, your eye pressure will be measured at each visit by using a probe to gently touch the eye. A numbing drop will be used so that you do not feel this. Steroid use may also increase the risk of infection. When you have an eye infection, your eye may become red, painful, itchy and watery.

Rubbing your eyes, washing your face, taking a shower, and going swimming will not make the insert be dislodged. You can use your normal eye drops while participating in this study such as artificial tears and prescribed medications. If you wear make-up, you can continue to do so during this study.

If any of these happen, please call Dr. Jennifer Harthan at the Illinois Eye Institute immediately for help or treatment. The phone number for the Illinois Eye Institute is 312-225-6200.

CONFIDENTIALITY

Every effort will be made to keep your information private. Your name or other identifying information will not be given out without your written permission. Data from this study may be used in professional presentations, but that data will not contain your name and will include the data from all of the research participants, not just yours. Information collected for the research will be stripped of identifiers and may be used in other research in the future.

COST OF THE STUDY

There is no cost for you to participate in this study. You will be paid $25 cash per visit. If you complete the study, you will receive $125 cash. You will receive a free month's supply of loteprednol etabonate ophthalmic gel drops at the beginning of the study to use for the duration of the study. You will be told which eye to use this medication in. Only information for the study will be assessed during your return exam, no other exams will be administered. The cost of your annual health examination, contact lens fitting, and contact lens materials will not be covered by this study.

CONTACT PERSONS

If you have questions concerning this study, you should contact Dr. Jennifer Harthan at (312)-949-7137. If you have questions concerning your rights as a research subject you are asked to contact Dr. Robert Donati (312)-949-7136, the person who oversees all research at the Illinois College of Optometry.

PARTICIPATION IN THIS STUDY

Your participation in this study is voluntary. You do not have to agree to do this study. You can stop being part of this study at any time. If you decide to not participate in this study, it will not affect your eye care at the Illinois Eye Institute. If you are a student, and you choose to not participate or withdraw from this study, it will not affect your eye care at the Illinois Eye Institute or your academic status at the Illinois College of Optometry.

I have read and understood the above information. I have had the opportunity to ask questions concerning this study and I agree to participate in this study.

Study Participant or Parent/Legal Guardian name (printed and signature with date)

_____
Print

_____ Date_____
Signature

Witness Signature

_____ Date_____