**RESEARCH SUBJECT CONSENT FORM**

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| **TITLE:** | In Clinic O**p**tometrist Inse**r**tion of D**e**xtenza **P**rior to C**a**taract Su**r**g**e**ry |
| **PROTOCOL NO.:** | The Prepare Study<br>IRB Protocol #20212533 |
| **SPONSOR:** | Vance Thompson Vision |
| **INVESTIGATOR:** | Mitchel Ibach, OD<br>3101 W. 57th Street<br>Sioux Falls, SD 57108<br>United States |
| **STUDY-RELATED PHONE NUMBER(S):** | 605-361-3937<br>605-361-3937 (24 hours) |

# RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

## What should I know about this research?

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

## How long will I be in this research?

We expect that your taking part in this research will last 4 months or less.

## Why is this research being done?

The purpose of this research is to evaluate the clinical outcomes with optometrist pre-surgical insertion of DEXTENZA in the clinical office setting in patients undergoing same-day cataract surgery compared to standard of care steroid therapy.

## What happens to me if I agree to take part in this research?

If you decide to take part in this research study, the general procedures include 8 visits, including two surgery day and 6 office visits. The study will have 2 groups, each patient will have one eye in each group. One group of 30 eyes will receive DEXTENZA and one group of 30 eyes will receive topical steroid drops. You will also receive topical antibiotic and NSAID drops to be used in both eyes post-operatively.

## Could being in this research hurt me?

The risks associated with participation in this clinical research study are expected to be similar to other therapeutic corticosteroid topical drop options for the treatment of postoperative pain and inflammation following cataract surgery and my include bacterial infections, viral infections, fungal infections, increased intraocular pressure, and glaucoma. Previous studies in adults have shown that treatment with DEXTENZA is generally well tolerated in a similar patient population that underwent ophthalmic surgery. The use of Dextenza in this study is considered investigational because it will be given before surgery instead of the approved standard of care when it is given after surgery.

## Will being in this research benefit me?

The most important benefits that you **may** expect from taking part in this research are reduction of pain and inflammation post-surgery, however this cannot be guaranteed.

## What other choices do I have besides taking part in this research?

Instead of being in this research, your choices may include a current standard of care topical corticosteroid ophthalmic drop regimen. Please discuss with your doctor other alternatives that may be available to you.

# DETAILED RESEARCH CONSENT

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

## What should I know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

## Why is this research being done?

The purpose of this research is to evaluate the clinical outcomes with optometrist pre-surgical insertion of DEXTENZA in the clinical office setting in patients undergoing same-day cataract surgery compared to standard of care steroid therapy. This is a prospective, single-center, open-label clinical trial; it is being conducted only here at your doctor's office, and both you and your physician will know the treatment type and dosage of the study medication.

The study drug, DEXTENZA, is approved by the FDA for the treatment of pain and inflammation following ophthalmic surgery. DEZTENZA is an intracanalicular (within the short channel near the inner corner of the eyelid) insert containing 0.4mg dexamethasone steroid designed to elute preservative-free drug over 30 days. The insert may remove the need for topical administration of dexamethasone (or other similar steroid) eye drops following surgery.

About 30 subjects will take part in this research.

## How long will I be in this research?

You will be scheduled for the following study visits: First and Second eye surgery days, the day after each surgery, and then Day 7, Day 30 and Day 90 following both eye surgeries. We expect that your taking part in this research will last approximately 3 months.

## What happens to me if I agree to take part in this research?

During the study, the following procedures will be done. Some of these exams will happen more than once while you are in the study.

- **Medical History and Concurrent Illnesses:** You will also be asked questions about your overall health, past diseases, and surgeries.
- **Concomitant Medications:** You will be asked questions about the medications, vitamins, or other supplements you take.
- **Demographics:** You will be asked questions such as your date of birth, race, and ethnic background.
- **Adverse Events:** You will be asked questions to find out whether you are having any changes in health or side effects during the study.
- **Ocular Pain Assessment on the Numerical Rating Scale (NRS Pain Scale):** You will be asked to rate your pain from 0 (no pain) to 10 (most pain).
- **Adapted COMTOL Questionnaire:** You will be asked questions about your personal experience and satisfaction with the study insert.
- **Eye Drop Burden Questionnaire:** You will be asked 8 questions about your experience administering the post-op drops.
- **Urine Pregnancy Test:** If you are a woman able to have children, you must have a pregnancy test by giving a urine sample.
    - The study doctor or staff will tell you if the pregnancy test results are positive. The results of the pregnancy testing must be negative for you to stay in the study.
- **Best Corrected Visual Acuity:** Your vision will be measured using an eye chart.

- **Slit-Lamp Biomicroscopy:** The study doctor will look into the front of your eye using a machine that has a bright light.
- **IOP (Intraocular Pressure):** You will have drops put in your eyes to numb them. Once your eyes are numb, the pressure inside of your eyes will be measured by using a machine that gently touches the surface of your eyes.
- **Dilated Fundus Examination:** The study doctor will put dilating drops in your eyes, once your eyes are dilated, the doctor will look at the back of your eye with a bright light.
- **OCT:** A special light beam will be used to take a picture of the back of your eye.
- **Insertion of Dextenza:** The study drug is a small insert that is placed in the punctum, a natural opening in the eye lid. The study doctor will first apply anesthetic drops to the eye to numb the eye. The study doctor will then place a small probe into the punctum to open the punctum to allow for the insert. The insert will then be placed into the punctum with forceps, which are like tweezers. Normal saline drops will then be applied to your eye.
- **Application of 1% prednisolone acetate:** You will be required to insert the drops 4 times a day for the first week, 3 times a day for the second week, 2 times a day for the third week, and once a day for the fourth week in the eye that did not receive the Dextenza insert.
- **Application of Moxifloxacin (Vigamox 0.5%) antibiotic drops:** You will be required to insert the drops 4 times a day for a week in both eyes.
- **Intracameral (into the front chamber of the eye) injection of NSAID (ketorolac) + antibiotic (moxifloxacin) + steroid (dexamethasone) combo (DMK):** You will be given an injection of standard operative medications during cataract surgery.
- **Application of NSAID (Prolensa) drops:** You will be required to apply the drops once every day for one month in both eyes.

## What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:

- Follow the instructions you are given.
- Come to the study clinic for all visits with the study doctor or study staff.
- Tell the study doctor or study staff about any changes in your health or the way you feel.
- Tell the study doctor or study staff about any changes in your medications or new medications you may have taken.
- Tell the study doctor or study staff if you want to stop being in the study at any time.

It is important for you to be honest with your study doctor about your medical history and any medicines or supplements you are taking in order to prevent any harm to you in taking part in this study.

## Could being in this research hurt me?

The risks associated with participation in this clinical research study are expected to be similar to other corticosteroid therapeutic options for the treatment of postoperative pain and inflammation following cataract surgery and may include bacterial infections, viral infections, fungal infections, increased intraocular pressure, and glaucoma. Previous studies in adults have shown that treatment with Dextenza is generally well tolerated in an appropriate patient population.

Dextenza may cause the following side effects. These include:

- Vision problems.
- Seeing "floaters" in your vision.
- Eye pain or redness.
- Feeling like something is in your eye.
- Eyelid swelling.
- Dry eyes.
- Headache.
- Visual sensitivity to light.

1% prednisolone acetate eye drops may cause stinging/burning of the eyes upon application. Use of these eye drops for a prolonged period of time or in high doses may cause serious eye problems such as high pressure inside the eyes and cataracts.

Moxifloxacin eye drops may cause the following side effects. These include:

- Red, irritated, itchy, or teary **eyes**.
- Blurred vision.
- **Eye** pain.
- Dry **eyes**.
- Broken blood vessels in the **eyes**.
- Runny nose.
- Cough.

Intracameral injection of NSAID + antibiotic + steroid combo (DMK) may cause the following side effects. These include:

- Eye irritation and infection.
- Eye burning/stinging.
- Headache.
- Fever.
- Tissue damage.
- Cornea problems.

NSAID (Prolensa) eye drops may cause the following side effects. These include:

- Visual sensitivity to light.
- Blurred vision.
- Eye pain or redness.
- Eye irritation or itching.
- Eyelid swelling.
- Bleeding in the eye.
- Headache.
- Conjunctival Hyperemia (increased amount of blood in the lining of the eye).

It is important that you tell the study staff about possible complications you experience while participating in the study. Not all risks can be predicted and there may be risks that are unknown at this time. If you have any health-related problems during your treatment, you should contact the Principal Investigator (Mitchel Ibach, OD) of the study at Vance Thompson Vision, Sioux Falls as soon as possible. It is not possible to predict in advance if any problems will develop, but if they do occur you will be promptly treated. The study protocol also permits your doctor to administer "rescue medication", or a different medication that he/she sees as an option for you in the case that Dextenza is not working for your pain and inflammation. A possible side effect to any of the drugs used in this study or the investigational drug is an allergic reaction. If you experience any allergic reactions, please notify the study doctor.

You cannot participate in this study if you are pregnant. If you are pregnant or become pregnant during the study, the study drugs may involve unforeseeable risks to the unborn baby.

## Will it cost me money to take part in this research?

There will be no additional cost to you for taking part in this research.

## Will being in this research benefit me?

There have been positive findings with use of the dexamethasone insert in the treatment of postoperative pain and inflammation. You may benefit by having your pain and inflammation reduced, however there is no promise your pain and inflammation will be reduced. Information from this study might help researchers to come up with new tests or medications to help others in the future.

## What other choices do I have besides taking part in this research?

There are other treatments available for postoperative pain and inflammation.

Currently, corticosteroid ophthalmic topical drops are used for the treatment of postoperative pain and inflammation in cataract surgery.

You do not need to participate in this study to be treated for your condition. You should discuss your alternatives to participating in this research with the study doctor or study staff. In addition, you may discuss your options with your regular health care provider.

## What happens to the information collected for this research?

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration
- WCG IRB, the Institutional Review Board (IRB) that reviewed this research

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Data or specimens collected in this research might be deidentified and used for future research or distributed to another investigator for future research without your consent.

## Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

## What if I am injured because of taking part in this research?

In the event that you should be injured in the course of a research study, you will be provided with the necessary medical care at Vance Thompson Vision**.** However, this statement does not mean that either such medical care of hospitalization, if necessary, will be free of charge. Furthermore, we do not intend to provide you with compensation as a result of any injury.

## Can I be removed from this research without my approval?

The study doctor may end your participation in the study without your permission at any time. The Sponsor may also choose to terminate the entire study at any time. Possible reasons for removal include:

- It is in your best interest
- You have a side effect that requires stopping the research
- You need a treatment not allowed in this research
- You become pregnant
- The research is canceled by the FDA or the sponsor
- You are unable to take the research medication
- You are unable to keep your scheduled appointments

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research. If you are withdrawn from the study, you may be asked to have the appropriate medical tests and follow-up to evaluate your health and safety.

## What happens if I agree to be in this research, but I change my mind later?

Participation in this study is voluntary and it is entirely your decision whether or not you take part in this study. If after reading this information and talking with the medical staff you choose not to take part, or if you change your mind after agreeing and signing the consent form, for any reason, your decision will be respected. If you decide not to participate in this study, or end your participation for any reason, you may receive a standard treatment, and no prejudice or bias will be show toward you for routine medical care.

You can stop taking part in this study at any time. If you decide to take part in this study, but later withdraw for any reason, study data collected prior to your withdrawal may still be used.

If you decide to stop being part of the study, you should:

- tell the study doctor immediately.
- see the study doctor to be examined

If you withdraw your consent to participate in this study, then no new information will be collected from you with the exception of information for adverse events occurring at the time of your withdrawal.

For taking part in this research, you may be paid up to a total of $400 for completion of the study. You will be paid for the visits you complete. You will be compensated within 8 weeks of your final study visit. Your post-operative drops will also be provided to you at no charge.

## Statement of Consent:

Your signature documents your consent to take part in this research.

| Signature of adult subject capable of consent | Date |
|---|---|
| Signature of person obtaining consent | Date |