ÖZEL ESKİŞEHİR GÖZ SAĞLIĞI VE HASTALIKLARI DAL MERKEZİ

INFORMED CONSENT FOR LUCENTIS™ (RANIBIZUMAB) INTRAVITREAL INJECTION

Patient Name Surname : **BARCODE**
File Number :
Education :
Job :
State of mind : ……

GENERAL INFORMATION

This information is given to you to help you make an informed decision about having cataract and/or lens implant surgery. Once you have read this **Informed Consent**, you are encouraged to ask any questions you may still have about the procedure. It is impossible to list all of the possible risks and complications associated with surgery. Risks and complications that are considered to be unforeseeable, remote, or commonly known may not be specifically discussed in this consent.

INDICATIONS

Age-related macular degeneration (AMD) is the leading cause of blindness in people over 50 years of age. There are two types of macular degeneration: dry and wet. In the "wet" form of AMD, abnormal blood vessels grow in the back of the eye. Sometimes these vessels leak blood or fluid that causes blurred or distorted vision. Without treatment, vision loss may be quick and severe.

Refractory macular edema, or swelling around the macula, is edema that affects vision but does not respond adequately to the usual treatment methods. It can occur with retinal vein occlusion (RVO) and diabetes (a condition called diabetic macular edema or DME). Without effective treatment, vision loss could progress and become permanent.

POSSIBLE BENEFITS

Lucentis™ (ranibizumab) was approved for AMD and refractory macular edema in RVO and DME based upon research that shows that VEGF is one of the causes for the growth of the abnormal vessels and edema that cause these conditions. Some patients treated with Lucentis™ (ranibizumab) had less fluid and more normal-appearing maculas, and their vision improved. Lucentis™ (ranibizumab) is also used, therefore, to treat macular edema, or swelling of the macula in RVO and DME.

POSSIBLE LIMITATIONS AND ADMINISTRATION

The goal of treatment is to prevent further loss of vision. Although many patients have regained vision, the medication may not restore vision that has already been lost, and may not ultimately prevent further loss of vision caused by the disease. After the pupil is dilated and the eye is numbed with anesthesia, the medication is injected into the vitreous, or jelly-like substance in the back chamber of the eye. Lucentis™ (ranibizumab) is administered by an injection into your eye as needed at regular intervals (about every four weeks); your ophthalmologist will tell you how often you will receive the injection, and for how long.

ALTERNATIVES

You do not have to receive treatment for your condition, although without treatment, these diseases can lead to further vision loss and blindness, sometimes very quickly. Other forms of treatment are available. At present, there are three other FDA-approved treatments for neovascular age-related macular degeneration (AMD): photodynamic therapy with a drug called Visudyne™ (verteporfin) and injection into the eye of the drugs Macugen™ (pegaptanib) and Eylea™ (aflibercept). Although Visudyne™ (verteporfin) and Macugen™ (pegaptanib) have been proven to slow down the rate of visual loss, most people do not get back better vision. The results with Eylea™ (aflibercept) are similar to Lucentis™ (ranibizumab). Three drugs have been approved for RVO: Lucentis™ (ranibizumab), Eylea™ (aflibercept), and Ozurdex™ (dexamethasone). Some eye surgeons use an anti-VEGF drug called Avastin™ (bevacizumab) to treat AMD and refractory macular edema; this use of Avastin™ is off-label. Eye surgeons also use triamcinolone acetonide, a long-acting cortisone-like drug (Kenalog™, Triesence™, or Trivaris™) to treat eye conditions like yours. Your doctor will discuss with you the benefits and risks associated with these other choices of treatment.

COMPLICATIONS FROM THE MEDICATION AND INJECTION

Your condition may not get better or may become worse. Any or all of these complications may cause decreased vision and/or have a possibility of causing blindness. Additional procedures may be needed to treat these complications. During the follow-up visits or phone calls, you will be checked for possible side effects and the results will be discussed with you.

COMPLICATIONS OF LUCENTIS ™ (RANIBIZUMAB)

Possible complications and side effects of the procedure and administration of Lucentis™ (ranibizumab) include but are not limited to retinal detachment, cataract formation (clouding of the lens of the eye), glaucoma (increased pressure in the eye), hypotony (reduced pressure in the eye), damage to the retina or cornea (structures of the eye), and bleeding. There is also the possibility of an eye infection (endophthalmitis). You may receive eye drops with instructions on when to use them to reduce the possibility of this occurring. Any of these rare complications may lead to severe, permanent loss of vision.

There is a potential risk of arterial thromboembolic events (ATEs), defined as nonfatal stroke, nonfatal heart attack, and arterial death, following intravitreal use of anti-VEGF drugs. The rate of ATEs was low during the clinical trials. Whenever a medication is used in a large number of patients, a small number of coincidental life-threatening problems may occur that have no relationship to the treatment. Patients with diabetes are already at increased risk for heart attacks and strokes, and the clinical trial conducted in order to approve this drug for diabetic macular edema showed that diabetic patients had slightly more deaths. There were not many deaths, and the cause was typical of patients with advanced diabetic complications. It is not clear, therefore, whether the drug or the diabetes caused the deaths.

KNOWN RISKS OF INTRAVITREAL EYE INEJCTIONS

Patients receiving an injection of Lucentis™ (ranibizumab) may experience less severe side effects related to the pre-injection preparation procedure (eyelid speculum, anesthetic drops, dilating drops, antibiotic drops, povidone-iodine drops and the injection of the anesthetic). These side effects may include eye pain, subconjunctival hemorrhage (bloodshot eye), vitreous floaters, irregularity or swelling of the cornea, inflammation of the eye, and visual disturbances.

PATIENT RESPONSIBILITIES

I will immediately contact my ophthalmologist if any of the following signs of infection or other complications develop: pain, blurry or decreased vision, sensitivity to light, redness of the eye (compared to immediately after the injection), or discharge from the eye. I have been instructed NOT to rub my eyes or swim for three days after each injection. I will keep all post-injection appointments or scheduled telephone calls so my doctor can check for complications.

PATIENT'S ACCEPTANCE OF RISKS

Patient consent

I acknowledge that the doctor has explained;

- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/treatment options and their associated risks.
- My prognosis and the risks of not having the procedure.
- There is no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- The procedure may include a blood transfusion.
- Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
- If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
- A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.

DOCTOR NOTE: ……
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I have reviewed all three (3) pages of this Informed Consent. The cataract and/or lens implant surgery has been explained to me in terms that I understand. I have been informed about the possible benefits, risks, and contraindications associated with the surgery.

I understand that it is impossible for my doctor to inform me of every conceivable complication that may occur, and that there may be unforeseen risks. I have been given the opportunity to ask questions and have received satisfactory answers to my questions. I understand that no guarantee of a particular outcome has been given, and that my vision could become better or worse following surgery.

- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
- If my ophthalmologist has informed me that if I have a high degree of hyperopic (farsightedness) and/or that the axial length of my eye is short, I am at increases risk for a rare complication known as nanophthalmic choroidal effusion. This complication could result in difficulties completing the surgery and implanting a lens, or other problems.
- If my ophthalmologist has informed me that if I have a high degree of myopia (nearsightedness) and/or that the axial length of my eye is long, I am at increased risk for a retinal detachment, whether or not I have surgery. Retinal detachments can lead to vision loss or blindness. Recent studies indicate that risk doesn't increased by the surgery, although an older study using different techniques did find an increased risk.
- I authorize the physicians and other health care personnel involved in performing my cataract surgery and pre- and post-operative care to share with one another any information relating to my health, my vision, or my surgery that they deem relevant to providing me with care. I give my permission for Dr. …….. to use my photograph for display or promotion.

DOCTOR NOTE: ……

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PATIENT CONSENT

The above explanation has been read by/to me. The nature of my eye condition has been explained to me and the proposed treatment has been described. The risks, benefits, alternatives, and limitations of the treatment have been discussed with me. All my questions have been answered.

I hereby authorize Dr. _____ to administer the intravitreal injection of Lucentis™ (ranibizumab) in my _____ Right eye _____ Left eye at regular intervals as needed. This consent will be valid until I revoke it or my condition changes to the point that the risks and benefits of this medication for me are significantly different.

PATIENT'S NOTE:……

Date : …./…./……
Hour : ….:….

PATIENT:
Name-Surname : ..…..…….....
Signature :

Patient's Parent/ Legal Guardian (mother and father)/ Translater

Name-Surname :	..…..…….....	Name-Surname :	..…..…….....
Signature :		Signature :	

DOCTOR- Ophthalmologist:
Name-Surname : ...…….....

Stamp

Signature :