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# TREATMENT OF AGE-RELATED MACULAR DEGENERATION INTRAVITREAL INJECTION WITH RANIZUMAB (LUCENTIS) OR AFLIBERCEPT (EYLEA)

## Treatment leaflet and Patient Consent form

This leaflet provides information about the eye condition wet age-related macular degeneration (AMD). Treatment for wet AMD is by an injection into the back of the eye (known as an intravitreal injection). This leaflet is given to each patient and is explained to them by a doctor, nurse or other health professional. The patient is asked to give their consent to this treatment and to sign the form where appropriate. The form is kept in the medical record and a copy is provided to the patient.

### 1. WHAT IS AGE-RELATED MACULAR DEGENERATION?

Age-related macular degeneration (AMD) is an eye condition which is the leading cause of blindness in older people. There are two types of macular degeneration: dry and wet.

In the 'dry' form of AMD atrophy (or wearing out) of the fine cells in the macula (the centre of the retina) occur. No treatment has yet been proven to prevent or cure dry AMD, but research in this field continues. Currently low visual aids may be used to support vision. High dose multivitamins and anti-oxidants are thought to decrease the risk of progression in some cases.
In the 'wet' form of AMD, abnormal blood vessels grow under the macula and affect the centre of the vision. Often such vessels leak blood or fluid and cause blurred or distorted vision. Without treatment, central vision loss may be severe and rapid.

### 2. HOW IS AMD TREATED?

Treatment of AMD cannot undo the changes already present in the eye and the goal of treatment is therefore to prevent further loss of vision. Ranibizumab (Lucentis®, Novartis Pharmaceuticals UK Ltd) is a medicine given by injection into the eye and acts to slow or stop the growth of the abnormal blood vessels and leakage that cause AMD. Although some patients have regained vision, most patients' vision will stabilise after treatment, Lucentis (ranibizumab) injections may not restore vision that has already been lost, and does not always prevent further loss of vision caused by the disease. Aflibercept (Eylea) is a very similar anti-growth factor type drug that has recently become available. Studies suggest that it may not need to be given as frequently as Lucentis.

### 3. HOW IS TREATMENT GIVEN?

The pupil is dilated and the eye is numbed with anaesthetic drops and washed with iodine. The medication is injected into the vitreous humour, which is the jelly-like substance in the back chamber of the eye. Injections are repeated into your eye once a month for at least three months and later as needed at regular intervals. Mr Tanner will discuss with you how often you will receive the injection, and over what length of time. It is often necessary to attend for eye examinations and or injections on a monthly basis and perhaps for several years.

## 4. WHAT OTHER TREATMENT OPTIONS ARE AVAILABLE?

Other forms of treatment are available for some types of wet AMD. These include photodynamic therapy (PDT) using a 'cold laser' and with a drug called verteporfin (Visudyne®, Novartis Pharmaceuticals UK Ltd) and, in some very limited cases, treatment with conventional or 'hot' laser. Other injections are also sometimes used. However, these options are now used infrequently as experience with antigrowth factor drugs such as Lucentis and Eylea has increased.

You do not have to receive treatment for your condition. However, if you delay starting treatment, your central vision may continue to get worse over a fairly short time period and to the point where treatment may no longer help. Although AMD hardly ever causes complete blindness, it can reduce the vision to the point where it is only possible to see outlines (known as peripheral vision) or movement but no fine detail because of loss of central vision.

## 5. WHAT ARE THE RISKS OF TREATMENT?

**Complications of Lucentis in other body parts**
There is a theoretical increased risk of experiencing blood clots (such as may cause heart attack or stroke) after intravitreal administration of medicines that affect the growth of blood vessels, such as Lucentis. However, a low incidence of these events was seen in the clinical trials. We would normally check blood pressure before treatment. Patients with a history of a stroke may be at greater risk for another stroke. If you have had a stroke, please discuss this with Mr Tanner.

**Risks of intravitreal eye injections**
Serious complications of the intravitreal injection procedure include retinal detachment, cataract formation and infection (endophthalmitis) within the eye. Any of these serious complications may lead to severe, permanent loss of vision. In the clinical trials these complications occurred at a rate of less than 0.1% of injections. Other serious events such as inflammation within the eye and increased pressure in the eye occurred at a rate of less than 2% in the clinical trials. More common side effects may include eye pain, conjunctival haemorrhage (bloodshot eye), vitreous floaters, irregularity or swelling of the cornea, inflammation of the eye, and visual disturbances such as small specks in the vision.

**Infection control**
You will receive antibiotic eye drops to attempt reduce the possibility of infection occurring following injection. If there are any signs of eye/eyelid infection present on the day of your planned injection, your treatment may need to be re-booked for another time to allow control of such infection. Please inform your doctor or nurse if you have a sticky or discharging eye.

**Coincidental risks**
Whenever a medication is used in a large number of patients, coincidental problems may occur that could have no relationship to the treatment. For example, patients with high blood pressure or smokers are already at increased risk for heart attacks and strokes. If one of these patients being treated with Lucentis/Eylea suffers a heart attack or stroke, it may be caused by the high blood pressure and or smoking and not necessarily due to eye treatment.

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

## 6. AFTERCARE / PATIENT RESPONSIBILITIES

You can resume normal activities once you have been discharged from hospital.

Please use the post-procedure antibiotic drops as advised.

I will make urgent contact 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 and have been provided with antibiotic eye drops to take. I will keep all post-injection appointments, which may be monthly, or scheduled telephone calls so that staff can check for response to treatment and complications.

If you experience eye pain or loss of vision:

Please contact Mr Tanner's team on 0800 644 0700 or 0800 644 0900

Out of hours Main Hospital Switchboards are:

Princess Margaret Hospital, Windsor - 01753 743434

Spire Dunedin Hospital, Reading - 01189 587676

Circle Hospital, Reading - 0118 922 6888

Eye Casualty at Royal Berkshire Hospital, Reading - 0118 322 7162/3

Please read this form carefully. If you have any further questions, please ask - we are here to help you. You have the right to change your mind at any time, even after you have signed the form.

## 7. FURTHER INFORMATION

**If you would like further information on AMD there are many sources of advice available.**

**Royal National Institute of Blind People.** (RNIB) Find out more at www.rnib.org.uk or phone the RNIB Helpline on 0303 123 9999.

**The Macular Disease Society**. Find out more at www.maculardisease.org or phone the Macular Disease Society Helpline on 0845 241 2041.

**AMD Alliance International** provides information on early AMD detection, treatment, rehabilitation and support services, as well as new prevention suggestions. Find out more at www.amdalliance.com

The **NHS Direct website** explains macular degeneration in detail and can be contacted 24 hours a day on 0845 4647 or www.nhsdirect.nhs.uk

## 8. **PATIENT CONSENT**

Patient details

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 authorise Mr Tanner to administer intravitreal injections to my left right or both eyes at regular intervals as needed.

_____ _____
Patient's Signature Date

## 9. Confirmation of consent

I have confirmed with the patient that he or she has no further questions and wishes the procedure to go ahead.

Mr Vaughan Tanner …… Date ……..