Royal Berkshire NHS Foundation Trust

Patient information

Treatment of wet macular degeneration by intravitreal injection with Ranibizumab (Lucentis) or Aflibercept (Eylea): Information and consent

Introduction

You have an eye condition called wet age-related macular degeneration (AMD). Treatment for wet AMD is by a course of injections into the back (vitreous) cavity of the eye known as an intravitreal injection.

In order to undergo this treatment you have to give consent and sign the form where appropriate. You will be given a copy of the form and another copy is kept in your medical record.

Before you sign the consent form it is important that you fully understand the treatment you are about to have, including alternative treatments and any risks or side effects.

What is age-related macular degeneration?

Age-related macular degeneration (AMD) 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 cells occurs in the macula which is the centre of the retina, leaving a thin patch and poor central vision. No treatment is currently available to prevent or cure dry AMD, but research in this field continues. Low vision aids to provide magnification along with good lighting may be used to support failing near vision.

In the ‘wet’ form of AMD, abnormal blood vessels grow under the macula and affect the centre of the vision by leaking blood and or fluid and cause blurred or distorted vision. Without treatment, central vision loss may be severe and rapid.

It is possible to have wet AMD in one eye and dry in the other.

How is AMD treated?

Treatment of AMD cannot undo damage already present in the macula, the goal of treatment is to prevent further loss of vision rather than restore sight. However, some patients do notice an improvement in their vision. Ranibizumab (Lucentis) and Aflibercept (Eylea) are medicines given by injection into the anaesthetised eye and act to slow or stop the growth of the abnormal blood vessels and leakage that cause AMD. It is important to understand that Ranibizumab (Lucentis) and Aflibercept (Eylea) injections may not restore vision that has already been lost, and do not always prevent further loss of vision caused by the disease.

How is treatment given?

The pupil of your eye is dilated with drops, antibiotic drops are administered and most importantly the eye is numbed with anaesthetic drops. An iodine solution is used to clean the skin around the eye and Iodine drops are put into the eye to reduce the risk of infection. The medication is then injected into the vitreous humour, which is the back chamber of the eye. Further iodine and antibiotic drops are used after the injection too.

Ranibizumab (Lucentis) and Aflibercept (Eylea) injections are repeated once a month for at least three months and then as needed at regular intervals. Your ophthalmologist (eye doctor) will tell you how often you will receive the injections, and over what length of time. It is often necessary to attend for eye examinations and/or injections on a monthly basis and usually for several years.

What other treatment options are available?

Other forms of treatment are available for some specific types of wet AMD. These include photodynamic therapy (PDT) using a 'cold laser' combined with a drug called verteporfin (Visudyne) and radiation treatment (Oraya).These treatments will be explained to you by your eye doctor or nurse if appropriate.

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 to a point where treatment may no longer help. AMD hardly ever causes complete blindness but it can reduce vision to the point where it is only possible to see outlines or movement using peripheral vision but loss of fine detail because of loss of central vision.

What are the risks of treatment?

- Complications of Lucentis/Eylea in other parts of the body.

There is a theoretical small increased risk of experiencing blood clots such as a heart attack or stroke after intravitreal treatment with drugs including Lucentis / Eylea. A low incidence of these events was reported in the Lucentis clinical trials. Patients with a history of a stroke may be at greater risk of another stroke. If you have had a stroke/TIA or heart attack previously, please tell your eye doctor or nurse.

- Risks to the eye.

Serious rare complications of the intravitreal injection procedure include retinal detachment, bleeding in the eye and infection within the eye (endophthalmitis). Any of these serious complications may lead to severe, permanent loss of vision. In clinical trials and real world reports these complications occurred at a rate of less than 0.1% of injections (1 in every 1000 cases).

· Infection risks.

Please inform your doctor or nurse if you have a sticky eye or recent discharge from your eye as the treatment may have to be postponed.

· Other serious events.

Other serious events such as lens damage or cataract formation, inflammation within the eye and increased pressure in the eye occurred at a rate of less than 2% (less than 2 out of every 100).

· Common side effects.

More common side effects may include eye pain, abrasion of the cornea, conjunctival haemorrhage (bloodshot eye), vitreous floaters (small floating specks in the vision).

· 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 the treatment.

· The treatment might not be effective for you.

Your condition may not get better or may become worse despite these injections. It is possible to swap from one treatment to another if your eye does not respond to the initial drug. You will be informed if this is the case.

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.

It is important that you tell us if you are unable to attend any of your treatment appointments and let us know if you have a problem after a treatment.

Contact details for the Macula Service

- 0118 322 7169 option 5 (Monday to Friday 8.30am-5.00pm).
- If you have any further questions, please contact the Eye Unit at the Royal Berkshire Hospital (Reading) on 0118 322 8648 and leave a message (messages are retrieved periodically throughout the day).
- West Berkshire Community Hospital patients, please contact the RBH as above.
- Prince Charles Eye Unit (Windsor) patients please contact 01753 636 491.

Opening hours (emergencies only)

- Eye Casualty, Prince Charles Eye Unit, Windsor
  Monday to Friday 9.00am-5.00pm, Saturdays 9.00am-12.30pm. Closed Sundays & bank holidays.
- Eye Casualty: Royal Berkshire Hospital, Reading
  Monday to Friday 9.00am-5.00pm
  Saturday, Sundays & bank holidays 9.00am-12.30pm. Closed Christmas Day and New Year's Day.
- **Outside of Eye Casualty hours you should visit your nearest Emergency Department (A&E) and explain you have had a recent eye injection.**

Further information

If you would like further information on AMD there are many sources of advice available. Brochures/posters from many relevant patient support groups are available in the Eye Department. Please ask.

- 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 Macula Society. Find out more at www.macularsociety.org or phone the Macula 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 Website explains age-related macular degeneration in detail, visit www.nhs.uk.
- Visit the Trust website at www.royalberkshire.nhs.uk

This document can be made available in other languages and formats upon request.

RBFT Department of Ophthalmology
Info based upon the Royal College of Ophthalmologists AMD Consent Form, August 2009
Revised: February 2019 .Review due: February 2021

Patient consent form

Patient label

PATIENT COPY

Statement of health professional *(only complete if you have appropriate knowledge of this procedure as specified in the Royal Berkshire NHS Foundation Trust's 'consent policy').*

I have explained the procedure to the patient.
In particular in addition to the above I have explained the following risks:

Infection
Bleeding
Retinal detachment
Lens damage
Loss of vision
Stroke
Heart attack

Signature of health professional: _____

Job title: _____

Printed name: _____

Date: _____

Statement of the patient

Please read this form carefully. You should already have been offered a copy of this leaflet which describes the risks and benefits of Lucentis */* Eylea injections, but if you don't have one please ask for one now. 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.

I agree to and request to have the procedure described on this form and which is for a course of such treatment.

I understand that:

- It has not been guaranteed that a particular individual will perform the procedure. The person will, however, have the appropriate experience and training.
- Any procedure in addition to those described on this form will only be carried out if it is necessary to save my life, or to prevent serious harm to my health or to my sight.
- I have been told about additional procedures which may become necessary during or after my operation.

Patient responsibilities

- I will contact the Royal Berkshire Hospital 24-hour emergency eye service urgently 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 understand the importance of attending all injection appointments, which may be monthly.

Statement of interpreter *(where appropriate)*

- I have interpreted the information above to the best of my ability and in a way in which the patient can understand.
- Interpreter's signature: _____
- Printed name: _____
- Date: _____

Patient label

PATIENT COPY

Patient consent

The above explanation has been read by me/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 the eye doctor to administer a course of intravitreal injections of LUCENTIS / EYLEA*

to my RIGHT / LEFT / BOTH EYE(S)*. *Delete as applicable.*

_____ _____

Patient's signature Date

Confirmation of consent *(to be completed by a health professional when the patient comes in for the procedure, if the patient has signed the form in advance)*

On behalf of the team treating the patient, I have confirmed with the patient that he or she has no further questions and wishes the procedure to go ahead.

Signature: _____

Job title: _____

Printed name: _____

Date: _____

Patient label

HEALTH RECORD COPY

Patient consent

The above explanation has been read by me/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 the eye doctor to administer a course of intravitreal injections of LUCENTIS / EYLEA*

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Printed name: _____

Date: _____

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