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TREATMENT OF DIABETIC RETINOPATHY

Treatment leaflet and Patient Consent form

This leaflet provides information about the eye conditions proliferative diabetic retinopathy (new blood vessels) and diabetic maculopathy (leaky blood vessels). This leaflet is given to each patient and is explained to them by Mr Tanner or his team. The patient is asked to give their consent to this treatment and to sign the form where appropriate.

Laser Treatment

Diabetic retinopathy is traditionally treated with laser treatment. Early treatment prevents severe sight loss in most, but not all, cases.

Maculopathy:

Requires gentle treatment to the central part of the retina. Serious sight loss is prevented in 60% to 70% of cases.

Proliferative retinopathy:

Requires extensive laser treatment to the outer part of your retina that is used for peripheral and night vision. The treatment is called peripheral scatter/pan retinal laser photocoagulation (PRP).

Benefits of laser treatment:

The aim of laser treatment is to maintain vision, not improve it.

What will happen if I don't have the laser treatment?

It is likely that without this treatment, you may lose part or all of your sight. The benefits of laser treatment greatly outweigh the risks.

Risks of laser treatment for maculopathy;

Complications are rare. Some people may still see the laser grid pattern after treatment. Usually this continues for up to two months and, very occasionally for up to six months after treatment. 1 in 10 people might see a small but permanent blind spot close to the centre of their sight. The chance of you completely losing your central vision after laser treatment is around 1 in 300 (0.3%). Accidental laser burns cannot be completely avoided. You may find it difficult to keep still or may accidentally look at the laser as it fires although this is very rare. Occasionally, a laser burn to your retina may result in new blood vessels growing that may bleed and cause scarring to the central vision resulting in permanent loss of your central vision.

Risks of laser treatment for proliferative retinopathy (PRP):

Over 50% of people treated notice some difficulty with their night vision, 20% notice some loss of peripheral vision and some people have to stop driving because their peripheral vision has been reduced. PRP laser can result in macular swelling and, usually temporary, drop in central vision. Occasionally, some people have a bleed into the jelly that fills the eye and floaters may appear.

Outpatient procedure between 15 minutes and 40 minutes:

Before the laser is applied, a local anaesthetic is put into the eye to numb it, and drops are instilled to dilate the pupil. A contact lens is placed in the eye which helps to keep the lids open and focuses the laser beam. Usually, the treatment is not painful. Sometimes a dull thud sensation or a sharp pricking feeling can be felt. If you have had a number of laser sessions in the past and have felt discomfort, it is a good idea to take painkillers an hour before the treatment starts.

After the treatment:

Your vision may be blurry for a few hours, but your sight will return to its previous level over the next few hours. The operated eye can be sensitive to light so you may wish to bring dark glasses to wear to go home after the treatment. You may be aware of floaters in your vision, these should settle over a few weeks. **You will not be able to drive yourself home so you will need to arrange transport home after the procedure.** You will be able to go home after your operation, no post laser drops are required, but if you are using any drops regularly than you should carry on as usual. At home, if you experience some discomfort, take painkillers like paracetamol. You will usually be able to resume normal activities the next day, including driving. If you wear contact lenses, you can start again the next day.

INTRAVITREAL INJECTIONS

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 diabetic retinopathy. It may be used to treat either maculopathy or proliferative retinopathy but is currently only formally licenced for maculopathy. 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. However, recent studies suggest that Lucentis treated patients do better than laser treated patients with a greater percentage achieving some visual improvement. Hence, anti-VEGF injections are considered the new gold standard of therapy for eyes with centre-involving macular oedema and reduced vision

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.

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 four 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.

WHAT ARE THE RISKS OF TREATMENT?**Complications of antigrowth factor injections 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 approximately 1 in a 1000 (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

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.

AFTERCARE

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

Please use any post-procedure antibiotic drops as advised.

Please 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. Please do not excessively rub eyes or swim for three days after each injection. Post-injection appointments will usually be monthly with OCT scanning.

EMERGENCIES POST LASER OR INJECTION

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.

FURTHER INFORMATION

If you would like further information on Diabetic Retinopathy:

<http://www.nhs.uk/Conditions/Diabetic-retinopathy/Pages/Introduction.aspx>

<http://www.rnib.org.uk/eyehealth/eyeconditions/eyeconditionsdn/Pages/diabetes.aspx>

<http://www.rcophth.ac.uk/page.asp?section=451§ionTitle=Clinical+Guidelines>

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:

Macular laser

Pan retinal Laser

Lucentis Injections

Eylea Injections

To my:

Left

Right

Both eyes

at regular intervals as needed.

Patient's Signature

Date

1. 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