TREATMENT OF AGE-RELATED MACULAR DEGENERATION BY INTRAVITREAL INJECTION WITH RANIZUMAB (LUCENTIS)

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.

TREATMENT LEAFLET

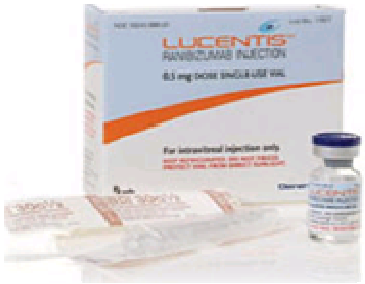
1 WHAT IS AGE-RELATED MACULAR DEGENERATION?

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

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?

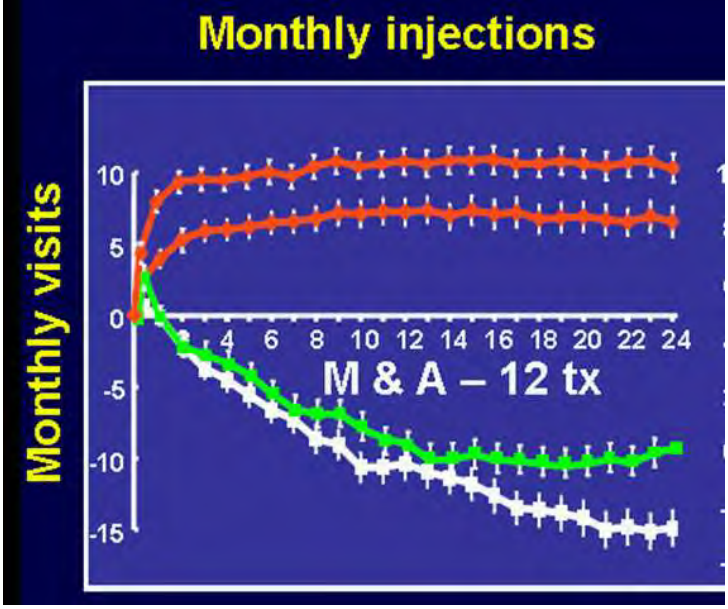


Treatment of AMD cannot undo the changes already present in the eye and the goal of treatment is therefore to prevent further loss of vision. Ranibizumab (Lucentis®, Novartis Pharmaceuticals UK Ltd) is a medicine given by injection into the eye and acts to slow or stop the growth of the abnormal blood 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.

3 HOW IS TREATMENT GIVEN?

The pupil is dilated and the eye is numbed with anaesthetic drops and washed with iodine. The medication (Lucentis) is injected into the vitreous humour, which is the jelly-like substance in the back chamber of the eye.

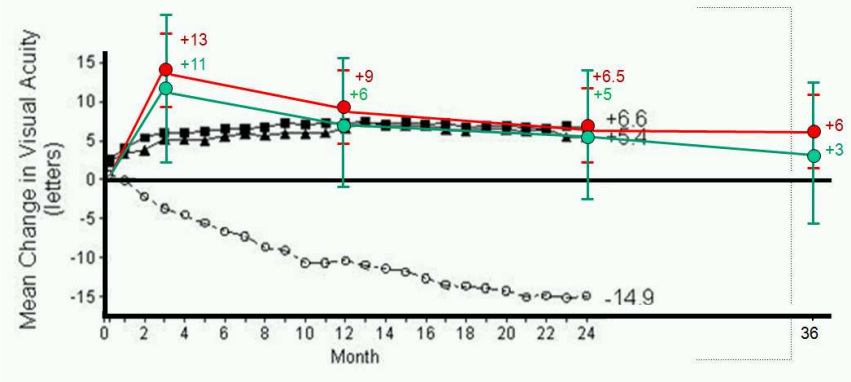
Lucentis (ranibizumab) injections are repeated into your eye once a month for at least three months and later as needed at regular intervals. Your ophthalmologist (eye doctor) will tell you how often you will receive the injection, and over what length of time. It is often necessary to attend for eye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



The results are obvious to see. The white line is without any treatment and the vision gets much worse. The Red lines are the trial results with monthly treatments.

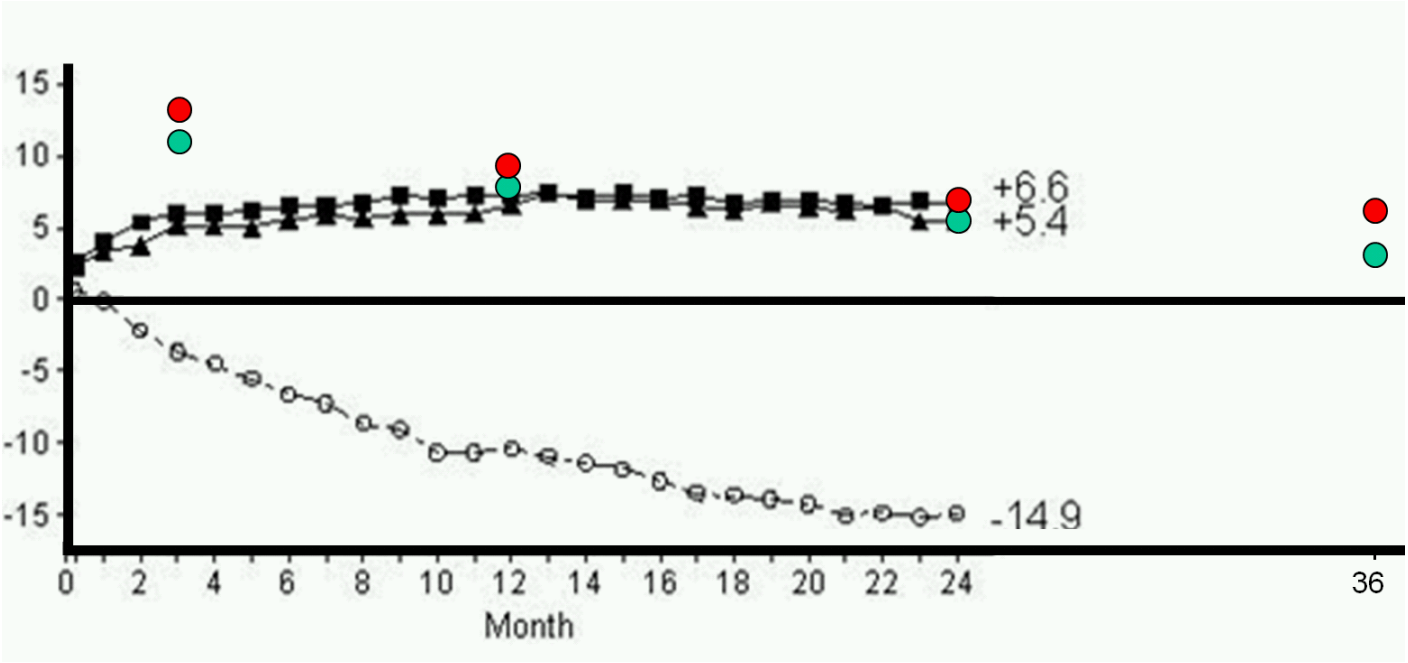
No statistics are needed to see the huge benefit of treatment.

TO the right is our Private Practice Results of Avastin (Bevacizumab) and Lucentis over 3 years superimposed on the strict clinical trial results. This shows that our results in clinical practice mirror the results of the very strictly controlled trails. This is very good news.



4 WHAT OTHER TREATMENT OPTIONS ARE AVAILABLE?

Avastin (Bevacizumab) was the original drug that they discovered had the effect of treating wet Age related macular degeneration. From this the drug Lucentis was derived. However Avastin (Bevacizumab) is made up by Moorfields Eye Hospital at a fraction of the price of Lucentis. Trials of the efficacy of Avastin (Bevacizumab) Vs Lucentis are ongoing with the UK and USA government.



Above is my results of Lucentis and Avastin (Bevacizumab) treatments in 100 pateints over 3 years compared to the Lucentis trials. The red and green points represent our results with Lucentis and Avastin (Bevacizumab). Despite the Patients in trials veing

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. Some other injections are sometimes used. These options will be explained to you by your eye doctor or nurse.

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 Lucentis clinical trials. 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 your eye doctor or nurse.

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 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 suffers a heart attack or stroke, it may be caused by the high blood pressure and or smoking and not necessarily due to Lucentis 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.

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

9 PATIENT RESPONSIBILITIES

I will contact Mr. Lee (01895 835144) or his team at The Hillingdon Hospital (01895 238282) or In the unlikely event that we cannot answer your call or we are away, you may always go to the accident and emergency department of The Western Eye Hospital (Marylebone Road) (0207 886 3247) which is open 24 hours a day where the on-call team will be happy to see you. Please mention that you are a Patient of Mr Lee and have had Avastin injections. 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.

10. **ASPIRIN** or **Clopidogrel**

If you are taking Aspirin Please stop this for a week before the injection. You may start it again immediately afterwards.

If Mr Lee has not discussed stopping aspirin for 3 months after your initial diagnosis of wet Age related macular degeneration, please discuss this with your General Practitioner or Mr Lee next time you see him. Aspirin makes things bleed as you know and this can be a problem with wet Age related macular degeneration and the injections hence why we ask you to stop this.

Please bring with you the antibiotic drops with you on the day of the injection.
You eye will probably be a little sore the next day and the vision a little blurred, this will settle by day 2. If it becomes more painful, red or blurred please Phone our office number.

Patient identifier Consent Form 3
Patient Agreement to investigation or treatment

Special language
Patient details (or Pre-printed label)

Re: {Salutation} {Forename} {Surname}
Of: {Address Line 1} {Address Line 2}
{Town} {County} {Postcode}
DOB: {Date Of Birth} - {Age} Years Old
{Man/Woman}
Barcode No {Patient Number}
Patient No. {User Field 1}
NHS number {NHS Number}

Division of Surgery
Department of Ophthalmology
The Hillingdon Hospital
Pield Heath Road
UXBRIDGE
Middlesex
UB8 3NN

Mr Lee/Prof Fielder Secretary 01895 279699
Mr Bloom Secretary 01895 279732
Nurses Station 01895 279223
Fax 01895 279247

Name of proposed procedure or course of treatment **(include brief explanation if medical term not clear)**

Intravitreal Injection of Lucentis into the eye monthly to 6 weekly for a year

C8920 or C7923 OPCS Code

Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

I have explained the procedure to the patient. In particular, I have explained:-

The intended benefits To treat your retinal condition. Lucentis is licensed in Europe/UK.

Serious or frequently occurring risks: Subconjuctival haemorrhage, Discomfort, infection – endophthalmitis, lens damage – cataract, retinal detachment, vitreous haemorrhage, failure to improve vision or control the eye condition. Concern over a slight increase in risk of heart attacks and strokes has been mentioned but no firm conclusion reached, thus a possible small increase may be present.

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of those involved.

The following leaflet/tape has been provided Lucentis leaflet 4 pages

Signed

…… {Today's Date}

Statement of interpreter (where appropriate)

I have interpreted the information above to the child and his or her parents to the best of my ability and in a way in which I believe they can understand.

Signed: …… Date: {Today's Date} Name (PRINT)

I agree to the procedure described above.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that the procedure will NOT involve local anaesthesia.

Patient's Signature {Today's Dat

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