

Patient agreement to investigation or treatment

Photodynamic therapy (PDT) for wet age-related macular degeneration (AMD)

Authors: Department of Ophthalmology

Brief description:

- You have been recommended photodynamic therapy (PDT) as the treatment for your wet age-related macular degeneration (AMD). Please expect to be in hospital for the whole day on your day of treatment.
- Here, we explain some of the aims, benefits and risks of this procedure. We want you to be informed to help you to be fully involved in your treatment.
- Please ask about anything you do not fully understand or wish to have explained in more detail.
- If you would like this information in another format or language or would like help completing the form, please ask a member of our staff.
- You will be asked to read this form carefully. You and your doctor (or other appropriate healthcare professional) will then sign it to document your consent.
- All our consent forms are available on the Addenbrooke's website:
<http://www.addenbrookes.org.uk/consent>
- Guidance for health professionals can be found on the Addenbrooke's intranet site
<http://nww.addenbrookes.nhs.uk/consent>
- Remember, you can change your mind about having the procedure at any time.

For staff use:

Does the patient have any special requirements? (e.g. requires an interpreter or other additional communication method)

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About photodynamic therapy for wet age-related macular degeneration

- The macula is the central part of the retina at the back of the eye. Many different conditions can damage the macula leading to serious visual problems. Age-related macular degeneration is a condition which occurs later in life.
- There are two types of age-related macular degeneration, usually referred to as 'wet' AMD and 'dry' AMD. This is not a description of what the eye feels like, but what the ophthalmologist (eye specialist) can see when examining the macula.
- Wet age-related macular degeneration (AMD) results from the development of abnormal blood vessels at the macula. These abnormal blood vessels cause fluid leakage, bleeding and scarring at the macula which lead to sight loss.
- Photodynamic therapy (PDT) slows or halts the development of these abnormal blood vessels at the macula. The treatment aims to preserve remaining useful vision. It should not be expected to improve your vision.
- A light-activated medicine called Visudyne[®] is used for this treatment which is given by an injection into a vein in your arm. This medicine accumulates in the abnormal blood vessels in your eye, where it is activated using a red laser light to treat your AMD.

Before your procedure

- When you arrive at the eye clinic, we will ask you for details of your medical history and carry out any necessary clinical examinations and investigations.
- We will put drops in your eyes to dilate your pupils which takes about 20 to 30 minutes. These drops will cause your vision to be temporarily blurred and will make your eyes more sensitive than usual to bright light for up to 24 hours.
- There will be an opportunity for you to ask us questions about the procedure during the time it takes for your pupils to dilate. However, please feel free to discuss any concerns you might have at any time.
- Many people will need to have a fluorescein angiogram (see below) which involves taking some photographs of the back of your eye. The ophthalmologist (eye specialist) uses these photographs to help with the assessment of your condition.
- If to your knowledge the answer to any of the following is **yes**, it is important that you tell us. Have you ever
 - received Human Growth Hormone
 - had brain surgery prior to 1992
 - or has anyone in your family been diagnosed with CJD

a positive answer will not preclude any treatment, it will however allow us to plan your operation so as to minimise any risks.

Fluorescein angiography

- A doctor (or specially trained nurse) will put a thin flexible tube (cannula) into a vein in your arm and inject a small quantity of fluorescein dye. The fluorescein dye travels to the blood vessels at the back of your eye enabling photographs to be taken using a specialised camera.
- A series of photographs of the blood vessels at the back of your eye will be taken using this specialised camera. This procedure takes about 10 minutes.

- Because some people can have an allergic reaction to the fluorescein dye, please tell the doctor if you are allergic to any medicines, food or animals; if you have asthma; if you have had a previous reaction to fluorescein; or if you are pregnant.

Possible side effects of fluorescein angiography:

- Fluorescein angiography involves injecting a special dye into a vein in your arm. There is a small risk (less than 1 in 200,000 people) of a serious allergic reaction to the fluorescein dye, which would require immediate treatment.
- The fluorescein dye will give your skin a slightly yellow tinge and will turn your urine bright yellow for a few hours following the procedure.
- If you have a mild allergic reaction, you might develop a transient rash or itch, which will gradually disappear after a couple of hours.
- Some patients feel a little nauseous (sick) during fluorescein angiography, which can usually be resolved by taking deep breaths.
- Occasionally, the fluorescein dye can leak out of the vein at the injection site which can cause some soreness for a few hours.

Photodynamic therapy (PDT)

- A doctor (or specially trained nurse) will give you an injection of Visudyne[®] (the light-activated medicine) through a flexible tube (cannula) in your arm, which will take about 10 minutes.
- A nurse will stay with you throughout this procedure.
- We will put some anaesthetic drops in your eye before the laser treatment. A contact lens will be placed on your eye for the laser treatment which helps the laser light to be focused on the affected area at the back of your eye.
- We will then carry out the laser treatment. This involves shining a special red laser light into your eye for 83 seconds.

Possible side effects of photodynamic therapy (PDT):

- The Visudyne[®] can leak out of the vein at the injection site which can cause pain, swelling, inflammation or bleeding.
- About 2% of patients experience some back pain while the Visudyne[®] is being given, which can be helped by moving around (eg walking a few paces) until the pain resolves.
- Some patients experience a temporary mild blurring of vision following treatment. If you do have any visual problems following treatment, we advise you not to drive or use machinery until the blurring disappears.
- Between 1% to 4% of patients experience a severe, but usually transient, decrease in vision in the treated eye following treatment.

Special measures you need to take AFTER photodynamic therapy (PDT):

- You will need to protect your skin from sunburn for 48 hours after the procedure because Visudyne[®] makes your skin more sensitive to light (photosensitivity).

- You will therefore need to avoid exposure to direct sunlight and bright indoor light (such as tanning salons, bright halogen lights or operating lights used by surgeons or dentists). 'Normal' indoor lighting is safe.
- If you are exposed to any of the above lights, please wear protective clothing and dark sunglasses to protect yourself. Sunscreens offer no protection.
- However, do not just stay in the dark, because exposure to normal indoor lighting will help your body clear the Visudyne® more quickly.

Follow-up appointments

Photodynamic therapy (PDT) usually involves a course of treatment over a period of two to three years. You will receive an appointment to review your progress around 3 months following each PDT treatment. If required, fluorescein angiography and photodynamic therapy (PDT) will be repeated as before.

Intended benefits of the procedure

Photodynamic therapy (PDT) can slow or halt the deterioration in your vision due to wet age-related macular degeneration (AMD). The aim of PDT treatment is, therefore, to preserve remaining useful vision. The PDT treatment should not be expected to improve your vision.

Alternative procedures that are available

You can decide not to have this type of treatment, and can be given advice about how to make the best use of your remaining sight.

Information and support

You will be given some additional patient information before and after the procedure. If you have any questions or anxieties you can contact one of the specialist nurses for photodynamic therapy, including Lindsay O'Shea, on Tel: 01223 274 600.

This document is also available in other languages, large print and audio format upon request – 01223 216032

本文件也可應要求，製作成其他語文或特大字體版本，也可製作成錄音帶。

Cantonese

આ દસ્તાવેજ વિનંતી કરવાથી બીજી ભાષાઓ, મોટા છાપેલા અક્ષરો અથવા ઓડિઓ રચનામાં પણ મળી રહેશે.

Gujarati

A richiesta questo documento è anche disponibile in altre lingue, a caratteri grandi e in formato audio.

Italian

ئەم بەلگەییە ھەر ھەروەھا بە زمانەکانی کە، بە چاپی درشت و بە شریتی تەسجیل دەس دەکەوێت

Kurdish

درخواست پر یہ دستاویز دیگر زبانوں میں، بڑے حروف کی چھپائی اور سننے والے ذرائع پر بھی میسر ہے۔

Urdu

Document History

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Consent Form (Adults)

Patient agreement to
investigation or treatment

<p>For staff use only: Surname: First names: Date of birth: Hospital no: Male/Female: (Use hospital identification label)</p>
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Responsible health professional/job title

Special requirements
(e.g. other language/other communication method)

Name of proposed procedure or course of treatment

Photodynamic therapy (PDT) for wet age-related macular degeneration (AMD) **Side (left/right).....**

Statement of health professional

(To be filled in by a health professional with an **appropriate knowledge of the proposed procedure**, as specified in the Hospital's consent policy)

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

- The intended benefits of the procedure
- Any serious or frequently occurring risks from the procedures including those specific to the patient
- Any extra procedures that might become necessary during the procedure

Blood transfusion Other procedure (please specify)

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

- The following information leaflet has been provided: Photodynamic therapy (PDT) for wet age-related macular degeneration (AMD)

Health professional's signature: Date:

Name (PRINT): Job title:
Contact details (if patient wishes to discuss details later)

I have offered the patient information about the procedure but s/he has declined information.

Statement of the interpreter (if appropriate)

I have interpreted the information to the best of my ability, and in a way in which I believe s/he can understand:

Interpreter's signature..... Date:

Name (PRINT):

Important notes: (tick if applicable)

- The patient has withdrawn consent (ask patient to sign/date here)
- See also advance directive/living will (eg Jehovah's Witness form)

Copy accepted by patient: yes / no (please circle)

For staff use only:

Surname:
First names:
Date of birth:
Hospital no:
Male/Female:
(Use hospital identification label)

Statement of patient

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy, which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. Do ask if you have any further questions. The staff at Addenbrooke's are here to help you. **You have the right to change your mind at any time before the procedure is undertaken, including after you have signed this form.**

Training doctors and other health professionals is essential to the continuation of the Health Service and improving the quality of care. Your treatment may provide an important opportunity for such training, where necessary under the careful supervision of a senior doctor. You may, however, decline to be involved in the formal training of medical and other students without this adversely affecting your care and treatment.

Please read the following:

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia.)

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

I understand that 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.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures that **I do not wish, without further discussion, to be carried out.**

.....
I understand that any tissue (including blood) removed as part of the procedure or treatment will be anonymised and may be used for teaching or quality control, and stored or disposed of in a manner regulated by appropriate, ethical, legal and professional standards.

I understand that all research will be approved by a research ethics committee and undertaken in accordance with appropriate ethical, legal and professional standards.

I understand that the research may be conducted within a hospital, university, not for profit organisation or a company laboratory.

Please tick boxes to indicate you either agree/disagree to the three points below. **Yes** **No**

I agree that tissue (including blood) not needed for my own diagnosis or treatment can be used for **research which may include genetic research.** If you wish to withdraw your consent for the use of your tissue (including blood) for research, please contact the Patient Advice and Liaison Service at Addenbrooke's Hospital.

I agree to the use of photography for the purpose of diagnosis and treatment.

I agree to anonymised photographs being used for medical teaching.

I confirm that the risks, benefits and alternatives of this procedure have been discussed with me and I have read and understood the above and agree to the procedure (or course of treatment) on this form.

Patient's signature: **Date:**

Name (PRINT):

If the patient is unable to sign but has indicated his/her consent, a witness should sign below. Young people may also like a parent to sign here (see guidance notes).

Witness' signature: **Date:**

Name (PRINT):

Confirmation of consent (to be completed by a health professional when the patient is admitted 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 s/he has no further questions and wishes the procedure to go ahead.

Signature Date:

Name (PRINT): Job Title: