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Early Detection of Neovascular Age-related macular degeneration (AMD)

# PATIENT INFORMATION LEAFLET

## The EDNA study: Early Detection of Neovascular Age-related macular degeneration (AMD)

We would like to invite you to be part of our clinical research study. We are investigating tests which can be used to help diagnose the eye condition called “wet” (or neovascular) age-related macular degeneration (wet AMD).

This is an information sheet about the study which you should read carefully. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve for you.

Please do not hesitate to ask the doctor or any other staff involved in your care to explain any words or information that you do not understand. You can also contact the study office (see details at end). Talk to other people about the study if you wish.

If after reading this form and discussing it with your family and friends, you wish to take part in this study, one of our team will go through the information sheet with you and answer any questions you have.

## WHAT IS THIS STUDY AND WHAT IS ITS PURPOSE?

Wet AMD can cause sight loss if not treated, therefore picking it up early so that treatment can be started as soon as possible is important to help prevent sight loss. People with wet AMD in one eye have an increased possibility of developing the condition in the other eye, but we do not know how to predict when that will happen. This is one of the reasons why both eyes are checked at every clinic visit.

There are several ways in which the eye without wet AMD can be monitored in routine clinic visits. The sight is checked using a chart, patients are asked about any symptoms, the eye is examined, the back of the eye (retina) is scanned and patients are asked to complete an Amsler test chart (a sheet with straight lines on which any sight distortion can be marked out).

What we would like to do is to systematically collect the information to work out which of these measurements is best at picking up when wet AMD

develops. In addition we would like to collect blood samples to build a valuable research database. Details about this optional part of the study can be found on page 5.

## WHY HAVE I BEEN INVITED?

We are asking you to consider taking part in the study because you have been diagnosed with "wet" AMD in one eye. Your other eye is not affected but is at risk of developing the same condition. Therefore we would like to invite you to join our study which will collect the information that is being acquired at your clinic visits on the eye which does not have wet AMD. Hospitals all over the UK are taking part and around 600 people like you will be included in this study.

## DO I HAVE TO TAKE PART?

No, taking part is entirely voluntary. You may choose not to take part in this research study. If you choose not to take part this will not affect the standard of care you receive and your eyes will be monitored according to the usual practice within the department.

If you do decide to take part we will ask you to sign a consent form confirming your agreement. However, even after you have signed the form, you may leave the study at any time without giving a reason.

## WHAT WILL HAPPEN TO ME IF I TAKE PART?

If you would like to take part in the study you will be asked to sign a consent form to allow us to collect information on your recent visits to the eye clinic. You may also be asked to attend for a study visit to allow additional tests on your eyes to be carried out and to obtain more information from you about your health, if the records do not provide the desired amount of information.

After this, your eyes will be monitored by the clinical team according to usual practice. This will involve having a number of routine tests (as mentioned above) in your good eye to look for signs that may suggest early development of wet AMD. If any of these tests show signs which might suggest wet AMD may be developing in your good eye, we will organise a fluorescein scan for you to confirm if you have wet AMD in your good eye. The fluorescein scan involves injecting a dye into your circulation and is identical to the test which would have been performed by your doctor when you were diagnosed with wet AMD in the first eye.

We will follow your progress for 3 years. The research team will collect information about your eyes from your usual clinic appointments during this time. You will be asked to attend an EDNA study appointment at 18 months

and 36 months at which a fluorescein angiogram will be performed to ensure that there are no signs of wet AMD in your good eye.

If you become unable or unwilling to continue in EDNA we would withdraw you from the study. If this happens, with your permission we would keep the relevant information already collected about you for the study results. This information will remain confidential and will not be used for any other purpose.

## WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

It is unlikely that taking part will directly benefit you. However, it is possible that if subtle signs of wet AMD develop which are not detected at your clinic visit, and because the study team will be scrutinising your records in a systematic way, that in a few people this might result in earlier detection of wet AMD. Taking part will help us to develop more efficient ways of monitoring patients like you in the future.

## WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

Most of the information that the study will collect will come from the routine clinical appointments and pose no risks to you.

We will ask you to come in for up to 3 extra study visits: one at the beginning, one at 18 months and one at 36 months. At month 18 and 36 you will have a fluorescein angiogram. There is an extremely small risk that you might have a serious allergy to fluorescein dye. However this type of allergy would have been picked up at your first fluorescein angiogram when you were diagnosed with wet AMD and therefore, we believe, that any risk from an additional fluorescein angiogram is extremely low.

## DO I HAVE TO DO ANY THING SPECIAL?

No, your normal day-to-day activities are not restricted in any way.

## WHAT IF NEW INFORMATION THAT IS RELEVANT TO ME BECOMES AVAILABLE?

Any new data which becomes available which is relevant to your care during the study will be communicated to you.

## WHAT IF SOMETHING GOES WRONG?

We do not expect any harm to come to you by taking part in this study. All procedures and techniques are already being used in the NHS to treat

patients with wet AMD.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the research sponsors of this study (Queen's University Belfast) but you may have to pay your legal costs. Sponsor contact details are available through the research team.

Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms would be available to you.

## WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

Your personal details and any information you give to us will be strictly confidential and only available to the study team.

However, this information may be looked at by individuals from regulatory authorities, from the sponsor or from the NHS Trust to make sure that the study is being conducted appropriately, but your confidentiality will be protected at all times.

After you join the study, your personal details will be passed to the Centre for Healthcare Randomised Trials (CHaRT) at the University of Aberdeen who are co-ordinating the study. You will be given a unique study registration number which will be used to enter your data onto a secure website. All information about you will be coded with the registration number and will be stored securely. It will be treated as strictly confidential and nothing that might identify you will be revealed to any third party.

We will send a copy of the images taken of your eyes to Queen's University Belfast. These images will be labelled with a study number and will not contain your name. The images will include those which were taken to help diagnose your wet AMD before you decided whether to take part in this study, and those which are taken as part of your monitoring during this study. The staff at Queen's University Belfast will use specialised computer software to read these images and measure any wet AMD.

By signing this consent form you are allowing your medical information for this study to be checked, including information about your diagnosis, processed and reported as necessary for legitimate scientific purposes. This includes use in future medical research if you agree to this separate clause on the consent form.

We also ask your permission to inform your GP of your participation in this research study.

## WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The results may be presented at meetings and in publications. Your identity will not be disclosed in those presentations or publications.

## WHO IS ORGANISING AND FUNDING THE RESEARCH?

The Chief Investigator is Professor Usha Chakravarthy, a consultant ophthalmologist based at Queen's University Belfast and the research is being sponsored by the Queen's University Belfast. The study is organised by a group of researchers from across the UK and is being coordinated by the Centre for Healthcare Randomised Trials (CHaRT), a recognized facility at the University of Aberdeen. The EDNA study has been made possible by a grant from the National Institute for Health Research, Health Technology Assessment Programme.

## WHO HAS REVIEWED THIS STUDY?

This research study has been approved by the Office for Research Ethics Committees in Northern Ireland (ORECNI) which is an independent group of people (some medically trained, some not) who have assessed the treatment protocol to check that full information is given to prospective participants and that any risks of the study are reduced to a minimum.

## COLLECTING BLOOD SAMPLES

If you are interested in taking part in EDNA, we would also like to ask you to donate two blood samples that will aid future research into wet AMD. Blood donation is not a compulsory part of EDNA, it is an optional part of the study. You can choose not to provide the blood sample and still take part in EDNA.

We would like to take and store a blood sample when you join the study and at the point when you cease to be in the study. We will need to collect about 20ml of blood (roughly a dessert spoonful). We wish to use the blood sample to find ways of predicting disease development. Please initial the consent form if you agree to us collecting these samples.

## WHAT WILL HAPPEN TO MY BLOOD SAMPLES?

The blood sample will be processed so that the DNA (the genetic material) serum and plasma (the liquid part of the blood) will be stored. These will be tested to see if there are differences between individuals that might explain why some people develop wet AMD and some do not. This knowledge could

help patients in the future. The samples collected in this study will be sent to Queen's University Belfast for processing and will be stored securely in a biobank. Research using the samples will be conducted only after approval by a Research Ethics Committee. If you agree to donate a blood samples we ask that you grant advance authorisation for possible future research. If you agree, your blood will be labelled with a code and your personal details will be removed. The coding will maintain your confidentiality whilst allowing biological details to be analysed in the future. .You may also request at any time that your samples are removed from the biobank and destroyed.
In the future, your sample may help researchers in the public and private sector to develop a new product to diagnose, prevent or treat disease. If a new product results from the research undertaken with your sample you will not receive any compensation or payment. EDNA partners in the public sector may work together with commercial companies to develop products for the benefit of patient and donor care; and we hope that in time, such products are brought into use by the NHS to improve future health care.

**CONTACT FOR FURTHER INFORMATION**

You can obtain advice on macular degeneration and its treatment from the Macular Disease Society UK and the Royal National Institute for the Blind (contact details below). This patient information leaflet has been constructed with help from representatives from both of these organisations.

Macular Society:
Help line 0300 3030 111
Email: info@macularsociety.org
www.macularsociety.org

Royal National Institute of blind people:
Help line 0845 766 9999
Email: helpline@rnib.org.uk
www.rnib.org.uk

You may discuss any questions or concerns before, during or after this treatment protocol with an independent ophthalmologist appointed by the funder to oversee the conduct of the study (please contact through the office of the Chief Investigator or the study office, see below). If, at any time during or after treatment in this study, you have further questions about the research or your rights as a participant in the study, you may discuss them with any of the people listed below.

Do not sign the consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions. You will receive a copy of this information sheet and the signed consent form to keep.

**THANK YOU VERY MUCH FOR TAKING TIME TO READ THIS LEAFLET.**

**Trust Study Number:** *<local reference number to be inserted>*
**ORECNI reference:** **14/NI/1120**

## Chief investigator contact details:

Professor Usha Chakravarthy, Centre for Experimental Medicine, Queen's University Belfast

### Contact details for further information

**Local contact details:**
[contact details
For local researchers
Affix sticker here]

**Study office contact details:**

EDNA Study Office,
Centre for Healthcare Randomised Trials (CHaRT),
Health Services Research Unit,
University of Aberdeen,
3rd Floor Health Sciences Building
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NHS
National Institute for Health Research