Diabetic Macular Oedema and Diode Subthreshold Micropulse Laser (DIAMONDS)

PATIENT INFORMATION SHEET

You are being invited to take part in this research study called:

Diabetic Macular Oedema and Diode Subthreshold Micropulse Laser (DIAMONDS): A pragmatic, multicentre, allocation concealed, prospective, randomised, non-inferiority double-masked trial

Before you decide to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with your doctor or family and friends if you wish. Do not hesitate to ask us questions if there is anything you do not fully understand or if you would like more information.

What is the purpose of this study?

The purpose of the current study is to determine whether currently used standard lasers and the newer technology of subthreshold micropulse laser are equal or whether one is better than the other.

Diabetic retinopathy is the damage of the retina caused by diabetes. People with diabetes and diabetic retinopathy may lose vision as a result of developing what is called diabetic macular oedema (DMO).

DMO is the most common complication of diabetes in the back of the eye. In DMO fluid leaks in the centre of the retina; the accumulation of the fluid reduces the vision, as the retina (the layer in the back of the eye responsible for our sight) needs to be dry to work properly. If the fluid is left untreated, permanent and irreversible visual loss will occur.

The amount of fluid in the macula can be measured by doing a scan of the eye called optical coherence tomography (OCT). Depending on the amount of fluid present in the macula, people with DMO will be offered medicines known as anti-vascular endothelial growth factor (anti-VEGF) or laser treatment.

Laser treatment is most effective when the retina has been thickened by fluid, however only if it has been thickened up to a certain point (less than 400 microns in thickness as measured by the OCT). Laser treatment is often given to treat macular oedema in a single session; repeated sessions may be needed to dry the retina fully. The laser treatment is given in the outpatient's department and only requires a drop of local anaesthetic in the eye as the treatment is not painful.

Anti-VEGF drugs are given to people with thick retinas (400 microns or more). Anti-VEGF drugs need to be given by injection into each eye; as often patients have both eyes affected, the injections need to be given in both eyes. On average, on the first year of treatment, patients with DMO will require 8-9 injections; in subsequent years the number of injections needed is often less. The injections are given in the hospital by an Ophthalmologist (eye specialist) as an outpatient procedure; they are also given by specialist nurses (a nurse trained for this purpose). The injections require more anaesthesia than the laser as patients feel them more.

The National Institute of Health and Care Excellence (NICE), after having carefully reviewed all data available from studies that have been done comparing laser with anti-VEGF injections, found that laser treatment was effective in people with DMO and retinas that

were less than 400 microns in central retinal thickness, as measured by the OCT, and offers good value for money; better than anti-VEGF injections. This is important as the NHS does not have indefinite resources; money needs to be distributed appropriately so that the best treatments can be accessed by patients in the NHS.

For many years standard lasers were used to treat DMO. More recently, a new type of laser was developed, called a micropulse laser. It is not clear however, if this form of laser is better than the standard laser, or the same. All data available with this laser suggests that it is certainly not worse than then standard laser. The purpose of the current study is precisely to determine whether both of these lasers are equal or whether one is better than the other.

Why have I been chosen?

You are being invited to take part in this study because you have diabetic retinopathy and DMO. In addition your OCT scan showed that the centre of your retina is less 400 microns in thickness.

Do I have to take part?

No, taking part is voluntary. It is up to you to decide whether or not you would like to take part in this research study. If you do decide to take part you will be given this information leaflet to keep and will be asked to sign a study consent form. You are still free to withdraw at any time without giving a reason. If you decide not to take part in this study that will be alright and your care will not be affected.

What will happen if I decide to take part?

You will be further informed about the study and you will have a chance to ask questions. If then you are sure you wish to take part you will be asked to sign a consent form in which you are agreeing to be part of the study.

Then you will be examined during a first visit (called baseline visit) carefully. Your previous medical and eye history will be reviewed and a sample of your blood may be taken to look at how is the control of

your diabetes (a measure of your HbA1c will be obtained if there is no recent HbA1c available). If a blood sample is taken, once we have the HbA1c result the sample will be destroyed in accordance with the local hospital policy. Then, your central sight will be carefully measured. Your field of vision (peripheral vision) will be also checked carefully. Photographs of the back of your eye will be done and a scan (OCT) will be also done. Lastly, you will be asked to fill some questionnaires about how you perceive your sight is and how your sight may affect your life.

Once the above information is collected, then you will be ready to receive your laser treatment (laser treatment would be offered to you also even if you were not to participate in this study as this is a standard treatment for people with DMO when the retina is less than 400 microns in thickness). For people in the study, which laser is going to be used will be determined by chance (a process called "randomisation"). If by chance it is determined that you will receive standard treatment, standard treatment will be given to you. If, in contrast, by chance it is determine that you will receive the new micropulse laser, then you will receive micropulse laser. You will not know, however, which one you will receive so that your knowledge on the type of laser you are getting will not influence the results.

After the baseline treatment and the laser, we will be monitoring you very carefully. You will be in the study for 2 years and we will look carefully after you for that period of time. You will come to the clinic for the purpose of the study every 4 months after the baseline visit (for a total of 7 visits), provided that the laser is done in the baseline visit. If not, you will need also a visit for the laser to be applied.

At the visits 4, 8, 16 and 20 months your sight will be measured and your scans will be obtained (as it would be done if you were not in the study) and we will check with you if you have had any problems with the treatment.

At the visits 12 and 24 months all the tests done at the baseline visit (as explained above) will be done.

If a single session of laser is not enough to dry your retina, as it is standard practice, we will offer you more sessions of laser, if appropriate. If the laser does not seem to help you, we will offer you other alternative treatments, as we would do if you were not involved in the trial. We will guarantee that your participation in the study does not prevent you to get the best chance to improve or maintain your sight.

In addition, the doctor looking after you may decide whether he/she wishes to undertake a test at any point in time to evaluate the blood vessels in your retina using a dye test called fluorescein angiography. This test is routinely used to determine the health of the blood vessels in the eye of people with diabetes. It allows the doctor to see the blood vessels that are leaking the fluid into the retina causing the DMO.

What are the possible disadvantages to my taking part?

There would be no disadvantage to you for being involved in the study. The only issue is that at baseline and at the year 1 and 2 visits some extra tests will be done (testing of your peripheral vision and filling in the questionnaires), so your visit will take longer than it would if you were not part of the study.

What are the possible benefits to my taking part?

You may be helping you and others as, if one laser is determined to be better than the other, this laser will be used in the future to treat DMO.

Will my participation be kept confidential?

Any information collected about you during the course of the study will be kept strictly confidential and will only be seen by staff involved in the study (which may include hospital staff, staff from the Trial Co-ordinating Centre) and people from regulatory authorities who ensure

that studies such as this are carried out correctly. All of them will have a duty of confidentiality to you as a research participant. Your GP will also be notified that you are taking part in the study.
Some of the analysis for the study will be conducted by staff from the University of Warwick. The data they receive will be anonymised.

Images captured of your eyes will be anonymised and stored electronically on secure servers held in Queen's University Belfast.

The data from this study will be kept for at least five years after its conclusion and may be used in other research studies. If it is used in this way all personal identifiers will be removed and it will not be possible to identify any individual.

What will happen to the results of the research study?

Data from this research study will be published. However, all data will be published anonymously. It will contain no personal information so nobody will be able to identify the participants from any of the data/photographs published.

Who is organising and funding this study?

DIAMONDS is organised and led by Professor Noemi Lois, who is a consultant at the Belfast Health & Social Care Trust, Northern Ireland and a Clinical Professor in Ophthalmology at Queen's University Belfast. It is funded by a grant from the National Institute of Health Research (NIHR). The Clinical Trials Unit coordinating the study is the Northern Ireland Clinical Trials Unit (NICTU), Belfast Health & Social Care Trust. Patients from many locations in UK are participating in this trial as several Hospitals in UK are taking part on this study.

Who has reviewed the study?

This research has been reviewed by an independent group of people called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. Having reviewed the study, the Research Ethics Committee has given permission for the study to take place.

The research office at your hospital has also reviewed and approved this study too.

What if I have any questions, concerns or complaints about the study?

If you any questions about participation in this study or concerns about the way it has been carried out you should ask to speak to the researchers who will do their best to answer your questions.

What if something goes wrong?

Every effort will be made to ensure that no patient taking part in this study is put at risk or harmed in any way. As the treatment (laser) is regularly used in the NHS (the standard laser and the micropulse laser are both used to treat people with retinal problems) it is very unlikely that anything will go wrong as a result of taking part in this study.

If something does go wrong and you are harmed due to someone's negligence, then you may have grounds for legal action against your hospital, but you may have to pay your legal costs. If you remain unhappy and wish to complain formally, you can do this through the normal health service Complaints Procedure.

What happens if I do not want to carry on with the study?

You may withdraw from the study at any time without giving a reason. If you decide to withdraw, the care you will continue to receive will not be affected. In the event of withdrawing your consent, we may ask for your permission to use the data we have collected to date.

What are the costs and payments for taking part in this study?

You will not be compensated for taking part in this study. There will not be extra visits as a result of this study. The visits plan for the purpose of the study would be required for us to look after you also if you were not involved in the study.

The additional tests that will be performed for this study will be provided to you at no cost.

Thank you for taking the time to read this Patient Information Leaflet.

Who to contact for further information:

Rebecca Denham on
07889086927
Research Nurse

OR

Professor Noemi Lois
02890976462
Principal Investigator for Belfast HSC Trust