Participant Information Leaflet

Efficacy of the Telescopic Mirror Implant for Age-related Macular Degeneration: The MIRROR Trial

<Name of direct care physician> would like to invite you to take part in our research study. Joining the study is entirely voluntary. Before you decide whether or not you wish to take part, we would like you to understand why the research is being done and what it would involve for you. One of our team will be available either by phone or if you attend a screening visit, to go through this information leaflet with you, to help you decide whether or not you would like to take part and answer any questions you may have. We anticipate this should take about 20 minutes. Please feel free to talk to others about the study if you wish.

The first part of this Participant Information Leaflet tells you the purpose of the study and a brief explanation of what will happen to you during the study if you decide to take part. In the second part, we give you more detailed information about what will happen during the study. Please ask if anything is unclear.

What is the purpose of this study?

This study will address a key priority for patients with Age-Related Macular Degeneration (AMD) *"Are there ways of restoring sight loss for people with AMD?"*. There are approximately 600,000 individuals in the UK with AMD and who are visually impaired. Despite the availability of new improved treatments by injection for the "wet" form of AMD, no treatment exists for "atrophic or dry" AMD or for those who do not respond to treatment.

AMD typically leads to loss of central vision. Normal hand-held low vision aids, for example magnifying glasses can be helpful, however these are limited because the field of view is small and

they can be difficult to handle. Recently, a novel approach has been the use of a magnifying lens implanted into the eye. This is often described as an intraocular telescope.

The intraocular telescope is placed inside the eye at the time of cataract surgery or as a separate procedure, usually after cataract surgery has already been performed. Intraocular telescopes have several potential advantages in that the scanning technique of the eye is more natural with an implanted lens which should make reading easier. These devices are also considered to be more cosmetically appealing as they are placed inside the eye. Intraocular telescopes do not change focus and are set for distance viewing. Reading for near through the telescope is possible through reading glasses.

Several intraocular telescopes have recently become available but limited evidence exists in terms of how useful they are. Therefore, the National Institute for Health and Care Excellence (NICE) has been unable to make a recommendation for their routine use in the NHS.

A novel device called the **OriLens** uses mirrors in its design, which results in a smaller size of implant but maintains a high magnification and allows less reduction of peripheral visual field. The reduced size of this telescope also offers the potential for an easier and safer surgery and faster recovery. In addition, it is safe to have an MRI scan with the OriLens device implanted.

The aim of this trial is to provide good quality answers to the following questions.

- How good is the OriLens at improving vision and quality of life?
- How safe is the OriLens?
- Which patients do well with the device?

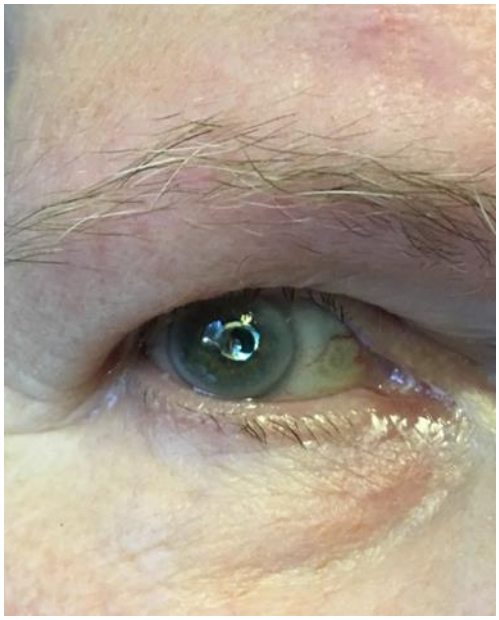

Figure 1. What the Orilens looks like when implanted

What does the study involve?

The study will involve 132 people with severe sight loss from AMD who have already had uncomplicated cataract surgery in both eyes. After consenting, patients will be examined for their suitability to participate in the study.

Sometimes, because we do not know which way of treating patients is best, we need to make comparisons. The trial will compare the OriLens with standard visual rehabilitation training with low vision aids. Participants will be allocated into groups, selected by a computer which has no information about the individual– i.e. by chance. Participants in each group then have a different treatment programme and these are compared. The treatments are described below. In this study, the individual will be randomly assigned into one of two groups:

Group 1: This will be the group who will undergo surgery and have the telescope implanted. Participants will receive the

OriLens telescope during an operation, will be tested for new glasses, provided with any necessary supplementary spectacles and low vision aids (LVAs), and will have three sessions of Low Vision Training.

Group 2: This will be the group that will have three sessions of Low Vision Training. Participants will be tested for new glasses, provided with appropriate spectacles and LVAs, and will have low vision training.

Those who are selected to receive the telescope will have surgery in one eye only which will be selected after testing of both eyes with an external telescope. The main measure to decide how good the telescope performs, will be distance vision after one year. The study will also measure how good the telescope is in improving reading vision, reading speed, quality of life and also how safe it is. The study will take place over a three and a half-year period and we plan to run the study in 10 hospital sites. Every effort will be made to spread the sites throughout the UK to allow access to all UK patients. Participant recruitment is planned to start in late 2016.

Once confirmed that the inclusion criteria to take part are met, each participant will have laser treatment to the capsule in the eye selected for study to make sure that the central vision is clear. This treatment is already standard practice after cataract surgery when the “capsule” becomes thickened. If you have already had this procedure in the eye selected for study, the procedure will not need to be repeated. The risks for laser treatment are very small and a full discussion of benefits and risks will take place with the operating surgeon. A separate NHS consent form will be signed before the procedure.

Once the study has ended, participants will continue to be followed up at Low Vision and Ophthalmology Clinics (as required) as is usual practice.

Why have I been chosen?

You are being invited to take part in this study because you have moderate to severe sight loss from AMD in both eyes with stable vision and have already had cataract surgery in both eyes.

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 sheet 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, the standard of care you receive will not be affected.

What are the possible benefits of taking part?

There is no guarantee that you will benefit from taking part in this study. The potential benefits of the study are that once enrolled, all participants will receive additional low vision training during the trial. Half of participants will also receive the telescope and it is anticipated that, as a result, they may get the additional benefit of magnified central vision. However, as this will involve surgery, there will be some risk involved.

What are the possible disadvantages of taking part?

The procedure for having the telescope implanted is similar to that for cataract surgery. This procedure will involve having a local anaesthetic and using drops afterwards for one month. As the cataract has already been removed from your eye, the procedure will only involve placing the telescope in the eye. The lens implant that is already in your eye will not be removed as it is needed for focusing your vision.

The main risk for any procedure involving surgery in the eye is infection. The risk will be the same as for cataract surgery which is approximately 1 in 800 patients. Antibiotics will be placed in your eye at the time of surgery to further reduce the risk of infection. It is usual to have some redness and mild discomfort for a few days after the surgery in your eye. The eye will usually be comfortable within 48 hours of surgery and will have healed well by one month. You may not be able to use the telescope straight away after the surgery. You will have training in how to use it at the follow up appointments.

Participation in the trial will not affect any other treatment that you may need for eye conditions including AMD. In particular, intraocular injections for AMD can still be given if needed.

For participants having surgery, full discussion of benefits and risks will take place with the operating surgeon. A separate NHS consent form will be signed before the procedure. If you have concerns about which eye is selected as the study eye, please discuss this with your surgeon.

What will happen if you agree to take part in the study?

If you would like to take part in the study, you will need to take the Pre-Screening Questionnaire to your optician, low vision clinic, optometrist, Ophthalmologist or GP for them to complete. There may be a small charge for this. This questionnaire will be reviewed by the research team at the nearest study site to your home and if you meet the initial criteria for selection, you will be invited to attend for screening appointments.

At the first appointment, a member of the research team will discuss the study with you and confirm that you agree to take part in the study. The research team will carry out a series of tests to confirm if you are eligible to take part. These tests are similar to

those which you may have had prior to cataract surgery. You will have your eyes examined and you will be given drops to enlarge your pupils. These drops can take 20 minutes to work and may make your vision blurry. It is important to make sure you have someone with you when you attend your appointment. These appointments may last up to three hours.

The research team will also look at the retina in your eyes using a dye test called fluorescein angiography and a scan. A dye is injected into a vein in your arm and from there will travel into your eye. It is likely that you have had this procedure carried out in the past. We like to know if patients are allergic to shellfish or iodine preparation beforehand, as sometimes these can interact with the dye used. Most patients have no difficulty with this test, however the risks associated with fluorescein angiography are mild or rare:

Mild: Nausea may occur in 7 out of 100 patients and vomiting in 1 out of 100 patients

Moderate: Hives (a skin rash) may occur in 1 out of 100 patients.

Severe: Breathing problems (Bronchospasm and laryngeal oedema). These severe reactions are serious but rare and can be treated successfully.

These reactions can be treated successfully, usually with an antihistamine which will be available at the time of the test.

You will then be asked some questions about your general health and the impact of your poor vision on your quality of life.

If you meet the eligibility criteria, you will be invited back to receive laser eye treatment in one eye. This is a short, painless and relatively simple procedure which usually takes about 15 minutes. You may have already had this treatment. If that is the case, you will not need to have it again. The laser eye treatment is considered very safe and you should be able to return to your

daily activities straight away. After you receive the laser treatment, a member of the research team will phone you to tell you which eye has been selected as the study eye and whether or not you will receive the telescope and Low Vision Training or Low Vision Training only.

Group 1: If you are to receive the telescope, you will be given an outpatient appointment for your surgery. The surgery will last approximately 30-40 minutes and is similar to what you would experience during cataract surgery. The visit will last about 2 hours. You will be asked to return to the hospital the following day, and again a week later, to have your eyes tested. You will also be asked to visit the clinic one month, three months, six months and one year after your surgery. You will be invited to attend for Low Vision Training at one month, three months and twelve months. During these appointments, which will likely last approximately 45 minutes, you will receive low vision aids and training in how to use them. You will also have more eye tests to check if there has been any change in your vision. In addition, you will be given a new spectacle prescription (if required) and a voucher towards the cost of your new spectacles.

Group 2: If you have been told that you will not receive the telescope, you will be given appointments at approximately one month, three months, six months and one year. You will be invited to attend for Low Vision training at one month, three months and twelve months. During these appointments, which will likely last approximately 45 minutes, you will receive low vision aids and training in how to use them. You will also have more eye tests to check if there has been any change in your vision. In addition, you will be given a new spectacle prescription (if required) and a voucher towards the cost of your new spectacles.

The last appointment is approximately one year after the laser eye treatment. You will not be required to attend any further appointments for this study.

Will my participation be kept confidential?

If you agree to take part in the study, we will be collecting information about your medical history, your eyesight and your quality of life. We will also ask about your health and social care service use.

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

Your GP will also be notified that you are taking part in the study.

The data from this study will be kept for at least five years after its conclusion.

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

You may receive a prescription, if required, for new spectacles and a voucher towards obtaining these spectacles. This voucher will cover the cost of basic glasses. If you would like to purchase designer frames, this will be at your own expense.

All other tests and procedures will be free of charge and of no cost to you. If you are eligible for the study, you will also receive £100 to help with travel expenses and subsistence at the end of screening visit two. This may not cover all your likely travel costs.

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. No personal information will be included and participants will not be identifiable from any of the data published.

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 East Midlands- Nottingham 1 Research Ethics Committee has given permission for the study to take place.

Who is organising and funding this study?

The MIRROR Trial is being organised and led by Miss Giuliana Silvestri, who is a Consultant Ophthalmic Surgeon at the Belfast Health & Social Care Trust, Northern Ireland. It is funded by a grant from the National Institute of Health Research. The Clinical Trials Unit coordinating the study is the Northern Ireland Clinical Trials Unit (NICTU), Belfast Health and Social Care Trust.

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

If you have 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; please use the contact details at the end of this document. If you are selected to receive the lens a device card (Annex 1.) will also be given to you after the procedure with contact details for further information. If you wish to make a complaint, you can do this following the normal health service Complaints Procedure.

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. 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 local health service Complaints Procedure by contacting <INSERT CONTACT DETAILS FOR COMPLAINTS SERVICE AT LOCAL HOSPITAL>.

What if new information becomes available?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your research doctor will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

Also, on receiving new information, your research doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue.

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 standard of care you receive will not be affected.

If you withdraw from this study before getting the OriLens telescope, you will not be contacted again about the study and you will be returned to standard care.

If you withdraw after laser treatment but before getting the OriLens telescope, you will not be contacted again about the study. You will be advised to visit your optometrist and you will receive standard care for your condition.

If you withdraw from the study after getting the OriLens telescope, you will be followed up by the operating surgeon and at the Low Vision Clinic on the NHS.

If you withdraw from the study after getting the OriLens telescope and wish to have the OriLens device removed, an appointment will be arranged for you with the operating surgeon to discuss the removal. This appointment will include discussing the reason why you wish to have the device removed and the potential risks and benefits of removing the device. If you chose to have the device removed, you will be returned to standard care.

In the event of withdrawing your consent, we may ask for your permission to use the data we have collected to date.

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

Who to contact for further information:

Chief Investigator:

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Principal Investigator:

Please insert name
Please insert address

Tel:
Email:

Research Nurse

Please insert name
Please insert address

Tel:
Email:

Annex 1.

Device card

Front of device

The MIRROR Trial

Name of patient:
DOB

I have a device called the OriLens in my <left / right> eye. This small implant provides magnification for easier vision.

It is safe to have an MRI scan with the OriLens device implanted

Back of device

The MIRROR Trial

For further information, please contact:
Name of Surgeon:
Site Address:
Contact No:

Name of Research Nurse:
Site address:
Contact No: