SEE AGAIN EUROPE

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Participant Information Sheet

Project Title	Double Intra-ocular Lens (IOL) implant for visual rehabilitation of patients with Age Related Macular Degeneration (ARMD)
Project Title	See Again 100 – 001
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Part 1

1. Invitation

We would like to invite you to find out if you are a suitable candidate to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you may have.

Part 1 tells you the purpose of this study and what will happen if you take part. Part 2 gives you more detailed information about the conduct of the study.

Ask if there is anything that is not clear.

2. What is the purpose of the study?

We are investigating whether a pair of intraocular lenses implanted into the eye which give a magnified image can improve vision of individuals with dry age-related macular degeneration (AMD). These lenses replace the natural lens - a similar procedure to a cataract operation. The lenses to be implanted are a modified design of an existing lens system and in addition are designed to divert to image to a healthy part of the macula to improve vision.

The procedure has been approved by NICE but has not yet been financially justified so that the NHS can make the procedure available for everyone.

3. Why have I been invited?

You suffer from dry ARMD and you have been invited to volunteer to find out if you are a suitable candidate to have the new double Intra-ocular lens system implanted into your eye with worst vision. About 10% of all dry ARMD sufferers will benefit from the procedure. A screening test will indicate if you are likely to benefit

from having the procedure performed. Only sufferers that are likely to benefit from the procedure will be invited to have the procedure performed.

4. Do I have to take part?

Taking part is entirely voluntary; it is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part and are assessed as being suitable, we will ask you to sign a consent form to perform the procedure. You are free to withdraw at any time, without giving a reason. This will not affect the standard of care you receive.

5. What happens to me if I take part?

The following table provides a summary of what happens

Timing	Activity
Up to 1 month before the procedure	You will visit the Consultant Ophthalmic Surgeon in South Manchester who will perform the procedure for an assessment. He will explain what will happen and demonstrate the improvement in vision that you can expect. See Again will arrange transport for you to be taken to University of Manchester for your eyesight to be checked at the Optometry Clinic – the check will take approx 1 hr. If you have not been referred by your GP, the consultant surgeon will contact your GP to find out if there is any reason why you should not join the trial.
Day of the procedure	You will be a day patient at facilities in Merseyside and the Consultant will see you before performing the procedure. The procedure will be performed under local anaesthetic and will take 40 to 50 minutes. Performing the procedure may be audio recorded or photographed and used to help train future Ophthalmic surgeons. The Consultant will see you after performing the procedure. You will return home on the same day.
4 weeks after the procedure	You will have an eyesight test by the Consultant Ophthalmic Surgeon who performed the procedure to check that you have benefited from having the procedure performed. This may be performed after 2 and/or 4 weeks
8 weeks after the procedure	You will have an eyesight test by the Consultant Ophthalmic Surgeon who performed the procedure to check that you have benefited from having the procedure performed.
12 weeks after the procedure	If your eyesight has not stabilised after 8 weeks a further test by the Consultant Ophthalmic Surgeon to check that your sight has stabilised and he will advise if you need new glasses. At 12 weeks See Again will arrange transport for you to be taken to University of Manchester for your eyesight to be checked by the Optometry Clinic – the check will take approx 1 hr. The Optometry Clinic will advise you of the spectacles you need to maximise the improvement in your vision.
Up to 6 months after the procedure	The Consultant Ophthalmic Surgeon may request for you to return to confirm that your sight has stabilised.

6. Expenses and payments.

No expenses will be paid for participating in the trial. However, travel will be provided or travel expenses will be paid if the eyesight test is performed at a remote location.

7. What will I have to do?

You will have to attend the events summarised above (pre-procedure, procedure and post procedure). Once you have been tested and obtained a new pair of glasses (that you will have to purchase) it is a matter of living your life normally.

8. What are the alternatives for diagnosis and treatment?

Dietary supplements and eye training programmes can help dry ARMD sufferers but the vision of many ARMD patients continues to deteriorate.

The procedure is not a cure for dry ARMD but it does treat the symptoms in order to improve vision. The procedure is currently not available on the NHS but it is available privately at a cost of about £8,000 per eye.

9. What are the possible disadvantages and risks for taking part?

If any problems are encountered during or after the implantation procedure a set of the existing intraocular lenses will be implanted at no cost to the patient. The Consultant Ophthalmic Surgeon has successfully implanted over 200 sets of the existing intraocular lenses.

10. What are the side effects of any treatment received when taking part?

The potential risks are similar to those for cataract surgery – a procedure that is carried out thousands of times a year in the UK. Overall complications for cataract surgery are rare (less than 5%), ranging from mild to severe, namely:

Ecchymosis – Bruising of eye or eyelids (quite common). Rarely severe bleeding behind eyeball.

Allergy – Causing an itchy swollen eye (1:500). Usually settles.

Posterior capsular opacification – Clouding of the membrane behind the implant (1:100).

Posterior operative glaucoma – Raised pressure in eye. This may require treatment (1:50)

Cystoid macular oedema – Poor vision due to inflammatory fluid in the centre of the retina. This is commonly midland needs no treatment. It can be severe and require prolonged treatment (1:250)

Optical aberrations – Glare and starbursts in bright light conditions.

Iris damage – Leading to irregular pupil. This is optically insignificant.

Ptosis – Droopy eyelid. Can be surgically corrected.

Posterior capsular rupture and/or vitreous prolapse – A split in the thin back wall of the capsular sac. Requires a longer than average time to complete surgery. At higher risk of inflammation, glaucoma and reduced vision after surgery. May require a second operation.

Refractive surprise – Unexpectedly large (or different from expected) need for glasses (1:500). May require second operation.

Dropped nucleus – The posterior lens falls deeper in the eye, needing another operation to remove it (1:1,000)

Dislocation of lens implant – Movement of position of the new lens system – may require further surgery (1:2,000)

Suprachoroidal haemorrhage – Bleeding inside the eye which may require further surgery (1:1,000). Risk of blindness.

Corneal decompensation – Clouding of the normally clear front window of the eye (1:1,000). Can be painful. May need corneal graft to restore vision and/or comfort.

Detached retina – Peeling off the light sensitive layer within the eye (1:1,000). Requires further surgery to repair.

Endophthalmitis – Rare severe (usually painful) infection inside the eye, which can lead to blindness (1:1,000). Treated with powerful antibiotics into the eye, but with often poor outcomes.

Sympathetic Ophthalmitis – Inflammation occurring in sympathy in the fellow eye (1:17,000).

Death – Incredibly rare with modern anaesthetic techniques (1:150,000).

As well as the risks associated with cataract surgery, Diplopia (double vision) is a risk is specific to implanting a double IOL implant. The assessment procedure mimics the performance of the implanted double lens system and thereby should minimise the risk if no evidence is observed during the assessment test.

In addition to the physical risks outlined above it is possible a failed procedure may result in the patient having psychological issues. In the first instance the surgeon would provide counselling and determine if professional counselling is appropriate.

11. What are the possible benefits of taking part?

Your vision may improve to the level demonstrated at the assessment. We believe this will lead to improved mobility/navigation skills and lower dependence on community care and/or relatives. However, the procedure is not a cure for ARMD, it treats the symptoms of ARMD and at some time in the future your vision may start to deteriorate again.

12. What happens when the research study stops?

The Proof of Concept Trial will hopefully lead to a much larger trial.

The much larger trial will research into health care and community care costs. Your confidentiality will be assured at all times and See Again will not access your information longer than the agreed time period – 6 to 12 months after completion of the Proof of Concept Trial.

13. What if there is a problem?

Any complaint about the way you have been dealt with during the study or possible harm you may feel you have suffered will be addressed. The detailed information on this is given in Part 2.

14. Will my taking part be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. This includes any audio or video recordings. These will also be kept confidential and only used specifically for training Ophthalmic Surgeons to perform the procedure. The details are given in Part 2.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision. Ask us if there is anything that is not clear.

Part 2

1. What if relevant new information becomes available?

If new information about treating dry ARMD becomes available one of See Again's team will tell you and discuss what this means to this study.

2. What will happen if I don't want to carry on with the study?

You can decide to withdraw from the trial at anytime and all your information will be erased from the study.

3. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to someone from the See Again team who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting See Again, Fence House, Fence Avenue, Macclesfield, Cheshire, SK10 1LT or calling 07504 053 200.

In the event that something goes 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 See Again Europe Limited but you may have to pay your legal costs.

4. Will my taking part be kept confidential?

If you join the study, some parts of your medical and the data collected for the study, will be looked at by authorised persons from See Again and its partners in the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information that is collected about you during the course of the research will be kept strictly confidential, and any information about you that leaves See Again and its partners will have your name and address removed so that you cannot be recognised.

Data collected during in the study may be sent to associate researchers to countries where laws don't protect your privacy to the same extent as the law in the UK but See Again will take all reasonable steps to protect your privacy.

5. Involvement of the General Practitioner/Family doctor (GP)

Your permission will be sought to enable the Ophthalmic Surgeon to contact your GP find out if he knows of any reason why you should not join the trial. Your GP will be requested to provide the information he has on your ARMD, the condition of your eye, whether you have had cataract surgery, any diagnosis that could impede your ability to give informed consent, his view of your understanding of spoken and written English and if you are or have previously been involved in research.

6. Will any genetic tests be performed?

The study will not involve any genetic tests.

7. What will happen to the results of the research study?

The results of the research will be used to justify a larger trial.

A summary of the research findings will be made available to all participants.

The larger trial will aim to quantify the cost benefits of improving the vision of dry ARMD sufferers. This information will be used to influence the NHS and other European national health authorities to make the procedure available to all dry ARMD sufferers on the basis of a cost saving opportunity.

8. Who is organising and funding the research?

See Again Europe Limited is organising and funding the study. See Again is paying for the use of clinical facilities (approved by the Care Quality Commission) and funding the Academic Institutions involved in obtaining the information for the research.

See Again is the manufacturer of the Intra-ocular lenses that are implanted during the procedure.

9. Who has reviewed the study?

All research performed in clinical facilities (such as hospitals) is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. Before this study can start it must be reviewed and given a favourable opinion by the Research Ethics Committee.

10. Further information and contact details

Further information about this research project can be obtained from See Again, Fence House, Fence Avenue, Macclesfield, Cheshire, SK10 1LT or call 07504 053 200 or info@seeagain.co.uk or visit www.seeagain.co.uk .

Specific advice on whether you should participate in this study and the benefits you can expect to gain will be provided by the Consultant Ophthalmic Surgeon.

If at any time you are unhappy about the study you should call See Again on 07504 053 200.

What if something goes wrong?
Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. Please raise your concerns in the first instance with the Principal Investigator (that is the lead researcher) Brendan Moriarty, his contact details are at the end of this form. If you wish to make a more formal complaint, please contact See Again Europe Limited.

Which insurance provisions are in place?
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 Sponsor, See Again Europe Limited but you may have to pay your legal costs.

Contact details
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