Moorfields Eye Hospital NHS Foundation Trust

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NHS Foundation Trust
162 City Road, London EC1V 2PD
Phone: 020 7253 3411

PARTICIPANT INFORMATION SHEET

Study Title	A Prospective, Observational study for identification of biomarkers of disease progression in Intermediate Age-related Macular Degeneration and Geographic Atrophy
Short title:	PROBE-IGA
IRAS ID	330679
Study Sponsor	Moorfields Eye Hospital NHS Foundation Trust
Study Funder	Boehringer Ingelheim Ltd
Chief Investigator	Shruti Chandra Moorfields Eye Hospital 162, City Road, EC1V 2PD
Phone Number	020 7253 3411
REC Ref:	23/LO/0755

Invitation

You are being invited to take part in a research study. 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. Do not hesitate to ask us questions if there is anything that is not clear or if you would like more information.

Background

We would like to invite you to take part in our research study that will observe changes in the eye in patients who are above 50 years with signs of Age-Related Macular Degeneration (AMD).

Before you decide we would like you to understand why the research is being done and what it would involve for you. Please take the time to read the following information. Talk to your friends or family or GP about the study if you wish. One of our team members will go through the information sheet with

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you and answer any questions you have. We suggest this should take about 20 minutes. Ask us if there is anything that is not clear, or if you require any further information.

Take time to decide whether you wish to take part.

What is AMD?

The Macula is a small area of the retina (a layer of light sensitive nerve cells that line the back of your eye). When you look straight ahead what you see is being detected by your macula. It is used for fine detailed central vision that you use to read, watch TV, and recognise faces. In the early stages, people do not have any symptoms due to this condition.

Age Related Macular Degeneration or AMD occurs when the cells in the retina stop working so well. There are two types of AMD, 'wet' and 'dry'.

Dry AMD

Dry AMD develops when macular cells become damaged due to a build-up of waste material. This waste looks like yellow spots on the back of the eye called and are called 'drusen' This is the most common type and occurs in 9 out of 10 people and can take a long time for vision to be seriously affected. Drusen can occur as part of the normal aging process. You can have very small drusen which does not affect vision. However, if the drusen get bigger it can indicate early AMD.

Wet AMD

Wet AMD develops when abnormal blood vessels grow from underneath the macula and damage the cells. It can cause severe vision loss over a short period of time. This is sometimes known as late AMD.

What is the purpose of this study?

We are conducting this study to observe and record information about the changes over time that occur in the retina in patients that already have signs of dry AMD. To do this we want to collect medical histories and eye exam data that may be associated with dry AMD.

Why have I been invited to take part?

You have been asked to take part in this study because you are aged above 50 years and have signs of AMD in at least one eye. About 200 patients will be taking part.

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Do I have to take part?

No, it is up to you to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will ask you to sign a consent form. You can choose to leave the study at any time without giving a reason. Your future care will not be affected.

What are the risks and disadvantages of joining?

As the main part of the study is for data collection only, there are no direct risks and disadvantages of joining.

What are the benefits of joining?

There will be no direct benefit to you, but you will be making a contribution to science and there may be a benefit to the future development of healthcare provision. This study is being carried to observe changes in the eye only. The information we get from this study may help to improve future treatment of people with Age Related Macular Degeneration.

What will happen to me if I take part?

If you decide to take part, you will be asked to sign a consent form. You will be in the study for 1 year and will be asked to come for tests for a total of 4 visits over 1 year. The tests may be done over two days.

What tests are done?

We will do the following test to see if you are suitable for the study and you have consented to the study:

1. You will be asked questions about your medical history including smoking history, eyesight history, blood pressure measurement, height, and weight measurement.
2. Visual acuity test: This test how clearly you can see different sized letters on a chart with each of your eyes. Low lighting visual acuity: visual acuity test will be repeated holding a filter in front of each eye to determine how clearly you can see in low light conditions.
3. Biometry: This test is like an ultrasound for your eye it allows to measure the size of the eye.

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For the next tests drops will be put into your eyes to make the pupils larger. You might find that bright lights may hurt your eyes for 4-6 hours after the drops, sunglasses will help

4. Eye examination: An eye doctor or optometrist will examine the back of your eyes using a bright light. This will take about 5 minutes. This will include testing your eye function during flickering light.
5. Colour photographs will be taken of the retina in each eye, you will notice a bright flash after each of the photos is taken, this will not have any long-term effect on your eyes; this will take about 10 minutes.
6. Optical Coherence Tomography (OCT), infra-red reflectance, autofluorescence and OCT-angiography: this test is like an ultrasound for your eye it allows us to take several different types of pictures of the back of your eye. The test is quick and painless, for the test you will sit in front of a machine and a light beam will scan the retina in each eye this test lasts about 10 minutes.
7. Tests only for eyes with intermediate stage of AMD
    a. Dark Adaptation: This tests how quickly your eyes recover from a flash. During this test, you will sit in a dark room and look into a machine. There will be a bright flash of light and you will be asked to press a button when you see a coloured light. This test takes about 20 minutes.
    b. Visual field tests (microperimetry): For these tests you will put your chin on a rest and look into a machine. One eye will be covered with a patch, you should press a button when you see lights flashing on and off in machine. This test will be done in light and dark and may take up to 30 minutes.

What happens next?

Everyone who agrees to take part in the study will have undergone tests 1-7 listed above. The pictures of your eyes will be analysed and compared to your visual function to understand AMD progression.

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Below is a timetable detailing which tests are carried out at each visit:

	Baseline	**3rd Month**	**6th Month**	**12th Month End of Study**	**Withdrawal visit**
Visit number	Visit 1	Visit 2	Visit 3	Visit 4	
Visit window	+ 5 days	+/- 2 wks	+/- 2 wks	+/- 2 wks	
Informed Consent	X				
Demographics	X				
Medical/ocular/surgical history	X				
Smoking history	X				
Adverse events	X	X	X	X	X
Concomitant medications	X				
Vitals (BP, pulse)	X				
Height and Weight	X				
Slit lamp examination including LOC III score and IOP	X	X	X	X	X
Dilated Fundoscopy	X	X	X	X	X
VA assessment (BCVA, LLVA)	X	X	X	X	X
Biometry	X				
NIR/FAF/OCTA/OCT including EDI (Heidelberg Spectralis)	X	X	X	X	X
OCTA (Plex Elite)	X	X	X	X	X
Colour photographs	X			X	X
Optos UWF (colour & FAF)	X			X	X
Dark adaptation	X			X	
Microperimetry*	X		X	X	

**this test will be done only if patients are able to fix well.*

How long do visits take?

It is hard to specify how long you will be in the eye clinic for, but you should allow 3 hours for all the mandated tests to be completed. You are allowed to eat and drink during the waiting time and you will be able to drive home but may have some light sensitivity. We can also split the tests over 2 days.

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Will my taking part in this study be kept confidential?

If you choose to take part, some parts of your medical records and data collected for the study will be looked at by authorised persons in the Sponsor institution. Your data will also be checked by authorised people who check that the study is being carried out correctly. Everyone involved in this study will have a duty of confidentiality to you as a research participant and we will ensure that this is followed. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. Best ethical and legal practice will be followed to ensure that all information collected about you will be handled in confidence. We will inform your GP about your participation in this research project and of any findings significant to your general health that may come to light during the study. The results of the study may be published or shared with other researchers and commercial companies for scientific purposes, however your identity will not be revealed. In addition, the results will be made available to the study funder for further research.

Will I receive re-imbursement?

You will not receive any monetary compensation for taking part in the study. Patients will be offered a £10 voucher as a thank you and an acknowledgment of their participation in this study. Your willingness to take part, however, may in the future help doctors better understand and/or treat other patients who have your condition.

What will happen to the results of the study?

The researchers may publish one or more scientific papers and make presentations using the database. If any publications or presentations of the findings resulting from this research are made or given, the findings presented in them may include data resulting from your participation in the study, but you will not be identified in any such presentation. The fully anonymised data and retinal images will be shared with the study funder for further research and may also be shared with other researchers and commercial organisations in and outside the UK.

What if I no longer want to be part of the study?

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You are free to withdraw at any time without giving a reason. If you choose to withdraw:

- Your personal information will be retained in an archive so that a record remains of your initial consent and the withdrawal process.
- Should you wish, no further data will be retrieved from your health-related records and no new data from laboratory measurements will be added to the research databases; pre-existing data will not be used in further analysis wherever possible.
- Pre-existing data and data that has already been distributed to other researchers and/or commercial organisations cannot be destroyed.
- Once confirmation of your decision to withdraw is received, you will not be contacted again by the study team.

What if something goes wrong?

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated by members of staff, you may have experienced due to your participation in the research or National Health Service complaints mechanisms are available to you. Please ask your research doctor if you would like more information on this.

Who is organizing and funding this study?

The study is being organised by Moorfield Eye Hospital NHS Foundation Trust The study is funded by a grant from Boehringer Ingelheim Ltd. The doctors conducting the research are not being paid for recruiting the patients in the study, nor for looking after them, and they have no conflicts of interest.

Who has reviewed this study?

The Research Ethics Committee, which has responsibility for scrutinising all proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of research ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from Moorfields Eye Hospital NHS Foundation Trust and the NHS whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

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Further information

If you want more information before deciding or have any queries, please feel free to contact research Co-ordinator Rabiah Abbas Saud (Tel No: 0207 566 2285 or e-mail on rabiah.abbassaud@nhs.net).
If you are interested in finding out more information about how your data is managed, please contact the Data Protection Officer for Moorfields Eye Hospital on moorfields.ig@nhs.net.

I have some questions, who can I ask?

For further general information about the study, please contact your study doctor on the contact details mentioned above. For general information about research and your rights as a research participant please contact Patient Advice and Liaison Office (PALS) in Moorfields Eye Hospital on 02075662325.

Thank you for reading this information and considering taking part in the study.