New methods of assessing eye health

Participant Information Sheet

You are being invited to take part in a research project. Before you decide whether to take part, it is important for you to understand why the research is being undertaken and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. If there is anything that is not clear, please don’t hesitate to ask us. We are happy to provide further information.

1. What is the purpose of this study?

Age-related macular degeneration (AMD) is the leading cause of vision loss in the UK and mostly affects people over 60 years old. It is a condition that affects the part of the back of the eye responsible for central vision, called the macula. This makes activities like driving and reading more difficult.

This study is focused on obtaining measurements of the eye, involving two new pieces of equipment. The first one, called OCTA (Optical Coherence Tomography Angiography), can “see” the blood flow at the back of the eye. The second one, called IRD (Imaging Retinal Densitometer), measures the sensitivity of the eye to light when in darkness.

Previous studies have suggested that these measurements might be compromised in people with macular disease, like AMD. However, before studying people with macular disease, we need to obtain data from healthy people to determine what is ‘normal’. This work will be useful in understanding this disease better, which could then help the development of new treatments.

2. Why have I been invited to take part?

You have been invited because you don’t have an ocular disease and you live close to the research centre where this study is being undertaken.
3. Do I have to take part?

**No**, your participation in this research project is entirely voluntary and it is up to you to decide whether you want to take part. If you decide to not take part, you don’t have to give us any justification and it won’t affect any of your legal rights or any treatments or care you are being given to your macular condition. If you are a Cardiff University student, participation on this project will have no effect on your education or progression through your course.

If you decide to take part, we will discuss the research project with you and answer any questions you might have. Then, we will ask you to sign a Consent Form. You can withdraw your consent to participate at any time without a giving reason, even after signing the Consent Form.

4. What will taking part involve?

Taking part will involve two visits to the School of Optometry at Cardiff University. A summary of what will happen at each visit is given below.
1. The first stage involves collecting background information about your eyes and any family history of eye problems.

2. Then, we will measure your vision and examine the front of your eye, using techniques commonly used in a regular sight test.

3. At this point, we will need to put dilation drops into your eye to be tested, this will allow your pupil to open wider.

4. Once your pupil has been dilated (approximately 30 minutes after), we will start the Imaging Retinal Densitometry test. You will be asked to look into the device and sit still, the measurements will take 15-20 minutes. This will be done in complete darkness. This machine will look at the activity of cells in the back of your eye and see how they adapt to darkness.

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**Visit 2**

1. Like in visit 1, we will need to put drops your eye to be tested, which will allow your pupil to open wider.

2. We will repeat the Imaging Retinal Densitometry, which corresponds to point 4. of the first visit. This will help us assess the capability of this machine to repeat the results.

3. The final stage will involve taking pictures of the back of the eye which can tell us about the blood flow at the back of the eye and will take 5 to 10 minutes. For this we
use something called an OCT, which is also common in a regular sight test. If you are interested, the researcher can show you your pictures.

5. **Will I be paid for taking part?**

No, but reimbursement of reasonable travel expenses can be considered. Please speak to the researcher.

6. **What are the possible benefits of taking part?**

The benefit of taking part is to help us better understand macular degeneration which may help with future studies and treatments. If the researchers discover anything that indicates you should see another eye specialist or your GP, they will explain why and write to your GP with your permission but remember this is not a complete eye examination and does not replace regular appointments with your ophthalmologist and optometrist.

7. **What are the risks of taking part?**

This study is very safe, however the drops that enlarge the pupil may make your vision temporarily a little blurred and make you sensitive to bright lights; these effects last for about 6 hours. During this time, we advise you not to drive or to operate any dangerous machinery. Very rarely some people’s eyes become red and sore a few hours after putting in these eye drops. In the extremely unlikely event that this should occur you should contact any of us on the numbers shown below. If, however we are unavailable then you should attend eye casualty for assessment. The contact details can be found below.

**Eye Casualty at University Hospital Wales**

029 2074 3191

In the case of using these drops in eyes with narrow angle glaucoma, they might cause a precipitated attack. For that reason, we assess this angle prior to instilling the drops to ensure you don’t have this condition. If this risk is detected by the researcher, you may be withdrawn from the study.
8. **Will my results remain confidential?**

All information collected from (or about) you during the research project will be kept confidential and any personal information you provide will be managed in accordance with the data protection legislation. Please see ‘What will happen to my Personal Data?’ (below) for further information.

9. **What will happen to my Personal Data?**

All information collected during the study will be processed and stored securely by the researchers using password-protected systems. Your personal information will be coded and only the researchers will be able to identify you during the study. When the study is over, the data may be retained for use in future studies but will be anonymous from this point. All procedures are compliant with the General Data Protection Regulation (GDPR) EU/2016/679 and the Data Protection Act 2018.

After 1 year your personal data will be anonymised, meaning we will remove any identifiers that can identify you from the data you have provided. This anonymous information may be kept indefinitely and/or published in support of the research. Other personal data we may have collected, such as your consent to participate in the study will be kept for 15 years.

Cardiff University is the Data Controller and is committed to respecting and protecting your personal data in accordance with your expectations and Data Protection legislation. Further information about Data Protection, including your rights and details on how to lodge a complaint may be found at [https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection](https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection).

Under data protection law we have to specify the legal basis that we are relying on to process your personal data. We will process your personal data on the basis that doing so is necessary for our public task for scientific research purposes.
10. **What will happen to the results of this study?**

The study results will be analysed and presented at national and/or international meetings and may lead to publications in the scientific literature. Identities of participating volunteers will not be revealed in any resulting published material. If you wish to be provided with a summary of the research findings at the end of the study, please tick the appropriate box on the consent form.

11. **What if I have any questions or if I have a problem?**

If you do have a concern about any aspect of this study, you should ask to speak to the researchers (contact details below) who will do their best to answer your questions. In the unlikely event that harm should occur as a result of negligence, cover is provided by the Cardiff University insurance policy.

Should you have any questions relating to this research project, you may contact us during normal working hours: We are very happy to discuss any aspect of the study.

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<tr>
<td>Vera Silva</td>
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If you feel any complaint has not been handled to your satisfaction, you may contact the Chair of the School Research Ethics Committee who is independent of the research team:

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<tr>
<td>Prof Guggenheim</td>
<td><a href="mailto:GuggenheimJ1@cardiff.ac.uk">GuggenheimJ1@cardiff.ac.uk</a></td>
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If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone’s negligence, you may have grounds for legal action, but you may have to pay for it.
12. Who is funding and reviewing the research?

This study is funded by the Macular Society. This research project has been reviewed and given a favourable opinion by the School of Optometry & Vision Sciences Research Ethics Audit Committee, Cardiff University.

Thank you for taking time to read this information and for considering taking part in this research project. If you decide to participate, you will be given a copy of the Participant Information Sheet and a signed consent form to keep for your records.