Cardiff School of Optometry and Vision Sciences
Ysgol Optometreg a Gwyddorau'r Golwg

PARTICIPANT INFORMATION SHEET

Functional imaging of the outer retina using high fidelity imaging retinal densitometry: exploring the relationship between visual pigment kinetics and AMD pathology

You are being invited to take part in a research project. Before you decide whether or not 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.

Thank you for reading this.

1. What is the purpose of this research project?

Age-related macular degeneration (AMD) is a condition affecting the central retina (the light detecting layer) at the back of the eye, known as the macula, which is needed for detailed vision. This condition usually occurs in people aged 60 and over, becoming increasingly common with age and is currently one of the leading causes of both sight impairment and blindness globally. AMD can reduce quality of life and impacts day-to-day activities such as reading and driving.

This study will use a new technique called Imaging Retinal Densitometry (IRD) to investigate AMD and common features of the disease (eg. yellow deposits called drusen) that can be seen at the back of the eye to understand how the features affect the retina and patient visions, before sight is lost. This research will allow us to develop a better understanding of the disease, the eye and patients' vision, and we hope will allow us to improve detection of the early stage of the disease. Whilst early AMD currently has no treatments available, early detection may help to develop new treatments and help patients to get treatment earlier for the advanced disease, helping to prevent irreversible sight loss.

2. Why have I been invited to take part?

You have been invited because you fulfil the baseline requirements to take part – are in the required age group with either no AMD or have early or intermediate stage AMD and no other ocular diseases affecting your vision.

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 or not to take part. If you decide to take part, we will discuss the research project with you and ask you to sign a consent form. If you decide not to take part, you do not have to explain your reasons and it will not affect your legal rights. Your decision to take part or not to take part will not affect the care you receive.

You are free to withdraw your consent to participate in the research project at any time, without giving a reason, even after signing the consent form.

4. What will taking part involve?

History and Symptoms [10 minutes] First, you will have a discussion with the researcher (Krishna Pattni) about your medical and eye history to ensure that you are a suitable to participate in this study. This will include any issues you are currently having with your eyes, eye problems in your family, your general health and current medications.

Vision check [5 minutes] This will involve reading a letter chart, like that which you would read in a routine sight test. You will be asked to read the lowest line that you can see clearly.

Colour vision assessment [1 minute] We will check your colour vision by asking you to read a series of coloured numbers from a book known as the Ishihara test.

Ocular health assessment [5 minutes] This test will require you to put your chin on a chin rest, and the researcher will use a special microscope called a slit lamp to check the front and back of your eye, this test is commonly used as part of a routine sight test.

Pressure measurement [5 minutes] This test is commonly part of a routine eye exam, it is sometimes known as the 'air puff test'. We need to do this to make sure that the pressure inside the eye is at a safe level before dilating the pupil with the drops. You will be asked to rest your chin on a chin rest, the researcher will need to take three readings in each eye, you will feel a gentle puff of air on your eye each time.

Prescription measurement [5 minutes] A machine will be used to measure your prescription. You will be asked to rest your chin on a chin rest and look at a target inside the machine, it will automatically measure your spectacle prescription.

Pupil Dilation and dark adaptation [20 minutes] Should you pass all the previous tests then drops will be put into your eyes to dilate your pupils. While the drops take affect you will be required to sit in a dimly lit room for 20 minutes, this will also allow your eyes to adapt to the dark. These drops are needed so we can obtain a good view of the back of your eye.

Imaging Retinal Densitometry [20 minutes] An imaging retinal densitometer (IRD) is a special type of camera for taking images of the back of your eye. Like the cameras in your routine sight test, you will be asked to sit comfortably and place your head on a chinrest. After this, you will be asked to view a cross inside the device to keep your eyes steady. While recording you will see a multi-coloured changing background.

There will be several recordings, the first will take just a few minutes, the final one will be the longest, it will start with a bright light and then we will ask you to look at a cross on a coloured background for 10 minutes, it is important to move as little as possible and not look around.

Retinal photography and OCT scans [5 minutes] The final part of the visit will involve taking photos and a 3D scan (optical coherence tomography) of the back of your eyes. These tests will only take a few seconds each, you will be asked to place your chin on a chin rest and look at a target (a cross or spot) inside the device. When the researcher has focused the camera there will be a brief flash as it takes the photo.

5. Will I be paid for taking part?

No, but reasonable travel costs will be reimbursed on presentation of a receipt (up to £10).

6. What are the possible benefits of taking part?

There will be no direct advantages or benefits to you from taking part, but your contribution will help us understand the disease process for AMD in greater detail, which has the potential to aid in the development of treatment options for the early stages of the disease.

7. What are the possible risks of taking part?

Imaging retinal densitometry is a very safe procedure. However, to take a measurement, dilation drops will need to be instilled. These drops will temporarily enlarge the size of your pupils and are commonly used in clinical practice to help view the back of the eye. A common side effect of this is that it can temporarily make you more light sensitive and affect your vision until your pupil returns to its normal size (usually around 6-8 hours). For this reason, it is important that you do not drive to the appointment, that you make arrangements to return home without driving and that you do not drive for 6 hours after the drops have been instilled.

A rare potential side effect of this is that it can increase the pressure inside your eye (0.006% in the general population). To minimise this risk, you will have an eye health check prior to any procedures, carried out by a General Optical Council (GOC) registered optometrist. If it is deemed that you are at risk of this, you will be notified and excluded from this study in the interest of your safety. Following the drops, in the unlikely event you experience any eye pain and redness, you should attend A&E.

8. Have any precautions been taken to reduce the spread of Covid 19?

To reduce the risk of covid 19, all participants will be contacted by phone prior to their appointment to ensure that they are well and not experiencing any symptoms of covid 19. Hand sanitizer will be available on entry to the building and a one-way system has been implemented to help reduce the spread. Both the participant and researcher will

be required to wear face masks throughout the procedure and all contact surfaces will be sanitized before the participant enters the room, including tables, chairs, and chinrests. Two metre social distancing measures will be in place wherever possible, and if any contact needs (for example when dilation eye drops are instilled) to take place disposable surgical gloves will be worn. This is in accordance with the university policy:

(https://intranet.cardiff.ac.uk/staff/supporting-your-work/research-support/research-integrity-and-governance/conducting-human-participant-research).

9. Will my taking part in this research project be kept confidential?

All information that is collected about you during the course of this research will be kept strictly confidential in accordance with the General Data Protection Regulation (GDPR) EU/2016/679 and the Data Protection Act 2018. All information collected during the study will be processed and stored securely by the Cardiff University researchers using password-protected systems. We may share the data we collect with other researchers but will have your personal information coded so you cannot be recognised from it. We will process your personal data on the basis that doing so is necessary for our public task for scientific research purposes. However, anonymised data may be entered into a publicly accessible data repository.

Cardiff University is the sponsor for this study based in the United Kingdom. The principal investigator will be using information provided by you to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

One year after the study is completed, 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 following the end of the project.

Cardiff University is the Data Controller and is committed to respecting and protecting your personal data in accordance with Data Protection legislation. The University has a Data Protection Officer who can be contacted at: inforequest@cardiff.ac.uk

You can find out more about how we use your information here:
https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection

Cardiff University who will have access to information that identifies you will be people who need to contact you about the study or to audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

10. What will happen to my Personal Data?

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
- the legal basis under which Cardiff University processes your personal data for research
- Cardiff University's Data Protection Policy
- how to contact the Cardiff University Data Protection Officer
- how to contact the Information Commissioner's Office

may be found at:
https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection
If you do not have internet access, please ask and a hard copy of this information will be provided.

Personal information will be kept separate from recorded data, and common identifiers (numerical code) will be used to track data from each participant. These will only be available to investigators.

11. What will happen to the results of the research project?

The results of this study will be analysed and reported by Krishna Pattni at Cardiff School of Optometry and Vision Sciences for the purposes of a PhD. It is our intention to publish the results of the project in academic journals and present the findings at national and international conferences. Data in all cases will be anonymous and any personal data will be removed. If you wish to be provided with a summary of the results, please tick the box on the consent form. We will retain contact details for the sole purpose of contacting you with the results.

12. What if there is a problem?

If you have any questions, please feel free to ask the research team (contact details provided below), we are happy to discuss any concerns/queries you may have. Please do not send any personal information by email as this may not be secure.

Krishna Pattni	PattniK@cardiff.ac.uk	02920 874374
Ashley Wood	WoodA2@cardiff.ac.uk	02920 875063
Tom Margrain	MargrainTH@cardiff.ac.uk	02920 876118

If you would prefer to speak to someone independent of the study, you can contact Ben Mead:

Ben Mead MeadB@cardiff.ac.uk 02920 870502

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.

13. Who is organising and funding this research project?

The research is organised by Krishna Pattni in Cardiff University, supervised by Dr Ashley Wood and Professor Tom Margrain. The research is currently funded by The College of Optometrists.

14. Who has reviewed this research project?

This research project has been reviewed and given a favourable opinion by the Surrey NHS Ethics Committee.

15. Further information and contact details

Should you have any questions relating to this research project, you may contact us during normal working hours:

Email: PattniK@cardiff.ac.uk

Tel: 02920 874374

Address: Cardiff School of Optometry and Vision Sciences, Maindy Road, Cathays, CF24 4HQ

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