Participant Information Sheet

Control

A new instrument for the early detection and monitoring of Age Related Macular Degeneration (AMD)

II-LB-0712-20001

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[Version 1.2]

Version History

Date	Document	Version Number	Action	By
29/3/14	PIS.pdf	1.0	initial submission	JMFK
10/6/14	PIS.pdf	1.1	revised in response to reviewers comments, section added about age related macular disease and a list of medicines added	JMFK
10/6/14	PISPx.pdf	1.1	separate sheet for patient group duplicate of PIS but with no ARMD section	JMFK
20/6/14	PISPx.pdf	1.2	clearer instructions about	JMFK
	PIS.pdf	1.2	the effect of the drops	JMFK

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MANCHESTER 1824

The University of Manchester

Dark Adaptation Sensitivity and Specificity Study (DA3S)

Information Sheet

You are being invited to take part in a research study to investigate subtle vision changes with age. As we get older the ability to recover from a dazzling light changes, this recovery of our vision is sometimes called dark adaptation. This study is part of an NHS funded research project to consider the usefulness of measuring dark adaptation. Before you decide it is important for you to understand why the research is being done and what will be involved. Please take some time to read the following information carefully and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

What is the purpose of the study?

We have developed a device that can measure how well we adapt to seeing in poor light. The ability to see in dim light is a sensitive measure of the health of the eye. By recruiting people will healthy eyes as well as people with early stage macula disease we want to see how well the device can classify people, either as having healthy eyes or as having early macula disease.

What is Macular Disease?

When macular disease appears in later life it is called age-related macular degeneration (AMD). It usually affects people over 60 but can happen earlier. Age-related macular degeneration is the most common cause of sight loss in the developed world. In the UK over 500,000 people are affected. About half of these are registered as visually impaired.

Causes

There are a number of factors in the development of age-related macular degeneration. Unfortunately, because the exact cause is not known you may develop the condition even if you reduce your risk factors.

Age Age is the main risk factor. As we age, cell regeneration reduces. This increases the risk of developing the condition.

Smoking Smoking damages blood vessels and the structure of the eye. Smokers are three times more likely to develop macular degeneration than non-smokers.

Diet A poor diet lacking in fruit and vegetables may increase the risk of AMD. Antioxidants in fruit and vegetables protect the body against the effects of 'free radicals'. These are unstable molecules which damage cells or prevent cell repair. Alcohol destroys antioxidants. Obesity and a diet with lots of hydrogenated or saturated fats also increase the risk of developing age-related macular degeneration.

Further Information

The macular society is a great source of information about macular disease, their website can be found at http://www.macularsociety.org .

Who can take part?

People with early macula disease as well as those without eye health problems are suitable for this study. Candidates should be in good general health and be aged over 55 or under 75 years of age to take part, providing they have good eyesight. Some medical conditions are permitted and some others are excluded and this will be discussed more fully if you are interested in taking part. At the end of this information is a list of medicines that can have an effect on vision, especially in poor light.

Why have I been invited?

For the study 40 volunteers are required, all participants will have healthy eyes or early macula disease. The age range for the participants is 55-75 years old. If you fall in that age range and your eyes are sufficiently healthy you can take part in the study.

Do I have to take part?

You are not obliged to take part. If you do take part it is important that you satisfy yourself that you know every thing that you want to about the study. You can do this by reading this leaflet as well as talking to family and friends. You can contact the investigators, Dr Kelly or Dr Murray, or you can talk to someone

outside the study who is familiar with the type of measurements we are making, Dr Laura Patryas. See below for contact details.

At any point if you feel that you no longer want to continue you can leave the study, without having to explain or justify your action. There would be no penalty to you if you chose to leave the study prematurely.

If you are interested in taking part Dr Kelly will call you by telephone and ask you some questions to ensure that you can be included in the study. Once your suitability has been established and you are happy to proceed and appointment will be made to come to the Carys Bannister Building at The University of Manchester.

What will happen to me if I take part?

The visit will have a few distinct parts and they are highlighted below:

Consent

When you arrive you will have the opportunity to ask any questions you may have about the study and you will be asked to sign an informed consent form. You will be reimbursed for travel expenses (£15).

Baseline Measurements

After some basic questions about your general and eye health, some simple tests of your eyesight will be performed. You will be asked to read a letter chart. Then a measurement will be made of the pigments in your eye. This is done by asking you to watch a light and press a button when you notice that is flickering.

Examination of the front of the eye

Using a microscope the front of the eyes will be assessed. This will check whether the eye drops that enlarge (dilate) the pupil are safe to use. As a further check the pressure of the eye will be measured using the non contact tonometer (air-puff test).

Drops If the examination of the front of your is normal then some drops will be used to make your pupils larger. The drops will be put into both eyes, these sting for at most 30 seconds and may make your vision blurry for two hours afterwards. Many people after having these drops are not able to drive for a few hours, if you decide to take part we recommend that you have a driver or to use public transport.

Questionnaire

Then while the drops make your pupils large you will be asked some questions about your lifestyle and diet.

Measurement of Dark Adaptation

Before measuring your ability to adapt to a dark environment the size of your pupils will be found. Here you will look into a camera and the built in software will measure the size of the pupils. You will then use the device we are investigating to practice taking measurements. These measurements are only made on one eye. The eye chosen will be the one that has the best vision. Once you are happy with using the device a flash gun will be used to dazzle a portion of your vision. The dazzle will pass after a few minutes and it is the recovery from the dazzle that the device is designed to measure. You will look into the device and when you see the test light flicker you will press a button. This test will stop after 20 minutes.

Concluding Tests

To conclude the visit we will take photographs of the back of your eyes. This will be a assessed by an eye specialist who will grade the health of your macula. If there are any concerns about the photograph you will be contacted and given advice. The pressure of the eye will be checked again and you will be given a leaflet that tells you about the effect of the drops and has advice for you if you feel that your eyes are uncomfortable. Finally you will sign a form to conclude your visit.

Expenses and payments

You will be reimbursed travel expenses of £15.00.

What are the possible disadvantages and risks of taking part?

No risks particular to this study have been identified. A theoretical risk of a type of glaucoma relates to the use of dilating eye drops. However, before drops are put in the eye the front of the eye will be examined to assess the risk of the drops having an adverse effect. If the eye is normal drops will be put in and it will be explained to you what you should do if you find that your eyes are uncomfortable after the visit. You will also be given a leaflet explaining what to do. It might be best to travel to the clinic on public transport or to have someone drive you. This is because many people find after the drops that their vision is too blurry for them to drive safely

If the eye is considered at risk from the drops you will be referred to an eye specialist for further investigation.

Some participants become fatigued during their visit and this will be remedied by offering rest breaks and refreshments.

What are the possible benefits of taking part?

You will learn more about how your eyesight adapts to the light. You will also learn more about how lifestyle and diet can have an effect on your eyesight.

What happens when the research study stops?

You will be asked to sign an study exit form. When all participants have been seen the collected data will be analysed and included in a report to NIHR i4i the grant providing body who funded the study.

Will my taking part in the study be kept confidential?

Your personal details will be kept strictly confidential. If The University of Manchester or the regulatory authorities inspect the detailed study records (to ensure accuracy of the data), your identity might be revealed. Inspection of the files will be conducted by a suitably qualified person and your identity will only be traceable at the site of the work. Photographs or film recordings of your eyes may be taken and kept as a permanent record, for teaching purposes, or to appear in published articles, books, etc. You will not be identifiable from these images, but if it is necessary to reveal your identity (for instance if we needed to provide this to your GP) this will not be done without your permission. A copy of the data held on computer about you is available on request in accordance with the Data Protection Act.

What will happen to the results of the research study?

The results will be subjected to analysis and will be prepared for publication in a peer reviewed scientific journal or at a conference. Once accepted for publication a copy of the article can be sent to you if you wish.

Eye examinations

Any examination that takes place in this study is not designed to replace any eye examination that you would normally have with your optometrist. Regardless of your participation in this project, you should have your eyes examined every

two years (or more frequently, if advised by your optometrist), and if a contact lens wearer have your contact lenses checked every six months (or more frequently, if advised by your optometrist).

What if there is a problem?

This study has been approved by North West Centre of Research Ethics Committees approval reference NW/14/0210). The study sponsor and monitor is The University of Manchester.

Complaints

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If they are unable to resolve your concern or you wish to make a complaint regarding the study, please contact a University Research Practice and Governance Co-ordinator on 0161 275 7583 or 0161 275 8093 or by email to research.complaints@manchester.ac.uk.

Harm

In the event that something does go wrong and you are harmed or suffer loss as a result of taking part in the research you may have grounds for claiming compensation from The University of Manchester. In order to protect you, the University of Manchester has insurance in place that provides:

- compensation for non-negligent harm to research participants occasioned in circumstances that are under the control of the University,
- cover for legal liabilities for injury, loss of or damage to property, or financial loss arising from the Universitys actions or those of its staff or supervised students.

If you make a claim in respect of legal liability you may have to pay your legal costs.

Who is organising and funding the research?

The study is organised by Dr Ian Murray and is funded by NIHR i4i grant number II-LB-0712-20001.

Telephone: +44 161 306 3862
email: ian.j.murray@manchester.ac.uk

Who has reviewed the study?

The study has been reviewed by four external reviewers appointed by the grant providing body, NIHR i4i, as part of the grant application process. The reviewers found the study to be well founded and supported the application.

Your participation in this study is entirely voluntary and you may refuse to participate in it, or withdraw at any time without penalty.

Further information and contact details

If you have any questions please contact:
Dr Jeremiah MF Kelly,
Faculty of Life Sciences
Carys Bannister Building
Dover Street
The University of Manchester
Manchester
M13 9PL
United Kingdom

Telephone: +44 161 306 3862
email: jeremiah.kelly@manchester.ac.uk
Ethical Ref: TBC

For information about dark adaptation from someone not involved in the study please contact:
Laura Patryas,
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M13 9PL

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List of Medicines that can affect vision

Drug Name	Used to treat	BNF Section	What kind of drug
AMIODARONE HYDROCHLORIDE	Cardiovascular system	2.3	Anti-arrhythmic
LOMITAPIDE	” ”	2.12	Lipid-regulating
BUPRENORPHINE	Central nervous system	4.1	Substance dependence
CHLORPROMAZINE	” ”	4.2	Psychoses and related disorders
ETHAMBUTOL HYDROCHLORIDE	Infections	5.1	Antibacterial
FLUCONAZOLE	”	5.2	Antifungal
ITRACONAZOLE	”	5.2	”
MICAFUNGIN	”	5.2	”
EFAVIRENZ	”	5.3	Antiviral
CHLOROQUINE	”	5.4	Antiprotozoal
ERLOTINIB	Malignant disease	8.1	Cytotoxic
TRABECTEDIN	and immunosuppression	8.1	”
INTEFERON ALFA	” ”	8.2	Affects the immune response
FLUTAMIDE	” ”	8.3	Sex hormones and hormone
TAMOXIFEN	” ”	8.3	antagonists in malignant disease
DESFERRIOXAMINE MESILATE	Nutrition and blood	9.1	Anaemias and some other blood disorders

Drug Name	Used to treat	BNF Section	What kind of drug
LEFLUNOMIDE	Musculoskeletal and	10.1	Rheumatic diseases and gout
DANTROLENE SODIUM	joint diseases	10.2	Neuromuscular disorders
PILOCARPINE HYDROCHLORIDE	Ear, nose and oropharynx	12.3	Drugs acting on the oropharynx
ALITRETINOIN	Skin	13.5	Eczema and psoriasis
ISOTRETINOIN	”	13.6	Acne and rosacea

This list is not exhaustive and it would be best if you could bring a list of your medicines with you.