Accurately monitoring Parkinson’s disease and other Neurological disorders using a simple photograph of the eye

Participant information sheet. Parkinson’s disease.

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We would like to invite you to take part in our research study. To help you decide, we have provided information on why we are doing the research and what it would involve for you.

Please take time to read this information carefully, and ask us if there is anything that is not clear, or if you want more information.

What is the purpose of the study?

There is a great deal of excitement in the field of Parkinson’s disease research at the moment. We understand the disease in a lot more detail now and several drugs are coming through that we hope may be able to slow down the disease process. Many of these drugs will be going into clinical trials over the next few years.

However a big problem we have at the moment is we do not have a good way to monitor Parkinson’s disease so we do not have an easy way to determine whether these new drugs are working. The main option available at the moment is to examine patients over time and determine whether the disease is getting worse. But clinical examination is very variable and usually changes very slowly. The lack of an easy way to monitor Parkinson’s disease is markedly slowing down the development of new drugs and treatments.

We have recently shown that there are nerve cells on the surface of the eye which become damaged by Parkinson’s disease in exactly the same way as the nerve cells in the brain become damaged. It is very difficult to look at the nerve cells in the brain, but we can study the nerve cells on the eye by taking a simple photograph of the eye. This is done using a special camera very similar to the camera they use in the opticians to take a photograph of the eye.

We are hopeful that we can develop this photograph of the eye as a simple quick and completely painless way to monitor Parkinson’s disease. Our results in a small number of Parkinson’s disease patients were very promising. We now want to look at a larger number of Parkinson’s disease patients to make sure the technique is reliable.

If we can prove this technique works then we will be able to take a simple photograph of the eye to accurately monitor Parkinson’s disease. This would greatly speed up the development of new drugs.

Why have I been invited to take part?

We wish to take a simple photograph of the eye in people with Parkinson’s disease in order to find out whether we can use the photograph to monitor Parkinson’s disease.

Do I have to take part?

No, it is up to you to decide. We will go through the information sheet with you and give you a copy. If you decide not to take part this will not affect your clinical care. If you agree to take part, we will ask you to sign a consent form, and keep a copy for yourself, to show you have agreed this. However, you are free to withdraw from the study at any time and this will not affect your clinical care.

Where will the study be held?

The study assessments will be performed at the NIHR/Wellcome Trust Clinical Research Facility, University of Manchester.

What will the study involve for me?

If you agree to take part in the study, you would come to the NIHR/Wellcome Trust Clinical Research Facility, University of Manchester. We have a small amount of money to help with travel costs. The visit would take no more than an hour or so. During the visit we would collect some basic information about your condition and examine you to determine the severity of your condition. We would take a blood test on the first visit to exclude conditions such as diabetes. We would then take the simple eye photograph. This will be done using a machine that is routinely used to examine the eye and is called corneal confocal microscopy. This is a painless test that takes only one minute per eye to perform. A drop of local anaesthetic jelly will be given to numb the front of the eye and to reduce your blinking during the test period. The microscope will be placed so that it touches the jelly on the front of the eye. You will see a white light which does not harm your eye in any way and causes no pain. The pictures taken from the surface of your eye (your cornea) will be analysed

We want to know whether the eye photograph changes over time therefore you would be invited to come for this assessment on 3 occasions:-

1) first visit

2) second visit 1 year later
3) third visit 1 year after second visit.

What are the possible disadvantages of taking part?
There are no recognised risks of the procedure. However if you have any problems then please contact the Wellcome Trust Clinical Research Facility and arrangements will be made for you to be assessed. Alternatively you can contact your GP.

Will I be compensated for my part in the study?
We have a small amount of money available to pay for travel expenses if required. The maximum we can pay is £25 per visit. Please discuss this with your researcher.

What are the possible benefits of taking part?
There will be no direct benefit to you from taking part in the study. The study will hopefully enable us to develop a test that can help accurately monitor Parkinson's disease. This would markedly speed up the development of new treatments for Parkinson's disease

What if there is a problem?
Any complaint about possible harm you have suffered, or the way you have been dealt with during the study, will be addressed. Details of this are given in part two.

What will happen if I lose capacity to make decisions during the study?
If you lose capacity to make decisions during the study, we would hope that you would remain in the study. We would seek to find someone who could make decisions on your behalf (a consultee).

Will my taking part in the study be kept confidential?
Yes. We will follow legal and ethical practice and handle all information about you in confidence.

Who is funding the study?
The study is funded by the Michael J Fox Foundation, USA. This is the largest funder of Parkinson's disease research in the world.

Where will the results of the study be published?
The results of the study will be published in a scientific journal. When results are available, they will be published on the Michael J Fox Foundation website https://www.michaeljfox.org. You will not learn the results of your individual test.

Who will have access to the study data?
Individuals from the University of Manchester, NHS Trust or regulatory authorities may need to look at the study data to make sure that the research is being carried out appropriately. Please be assured that anyone accessing your data will have a duty of confidentiality to you as a research participant. Aside from this, data will only be accessed by the research team. The data collected during this study could be used to support research in the future. We may use the anonymous data in future studies or share it with other researchers working on other studies. All of the data

used for future research will be anonymised and so no-one will be able to identify you. Apart from your consent form, no other personal data will be stored.

What if I don't want to carry on with the study?
If you withdraw from the study, we would normally use any information collected up to this point unless you request us not to. We would not use any identifiable information.

What if there is a problem?
If you have a minor complaint then you need to contact the researcher(s) in the first instance. Please contact Dr. Monty Silverdale, the study Chief Investigator.
Email: Monty.silverdale@manchester.ac.uk
Tel: 0161 206 2574.

If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact the Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 275 2674 or 275 2046.

Will my taking part in the study be kept confidential?
Yes. Information about you that is collected as part of the study will be identified by a unique study number in order to maintain confidentiality. This data which cannot be used to identify you will be stored on a University computer.

Data which can be used to identify you will not be stored apart from the consent form. Non-identifiable data will be stored for 10 years.

If the study identifies results that may be important for your medical care, such as abnormal blood tests, then we will inform your GP.

What will happen to the results of the study?
Once the study is finished, we plan to publish the results in a medical journal so that others working in the same field will be aware of our findings.

Who is organising the research study?
The study is organised and sponsored by the University of Manchester. The study is insured by the University of Manchester insurance as well as by NHS insurance.

Who has reviewed the study?
The study has been given a favourable ethical opinion from North West - Haydock Research Ethics Committee.

Further information and contact details
Name: Dr Sze Hway Lim**********
Tel: 07766256349************
Email: sze.lim@srft.nhs.uk***********