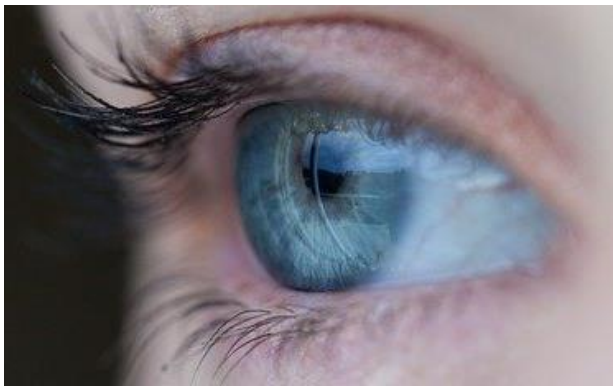
Clinical Evaluation of a Novel [Live] Optical Coherence Tomography (OCT) Device to Improve the Management of Eye Disease

We would like to invite you to take part in our research study. It's important that you know what this study is about, and what it involves, before you decide if you want to take part. You can talk about this with your family, friends, parents, guardians, support workers or anyone else you want to.

The Study

What is the research about?

We have created a scanner that allows us to see the layers of the cornea (the clear window at the front of the eye) more clearly.

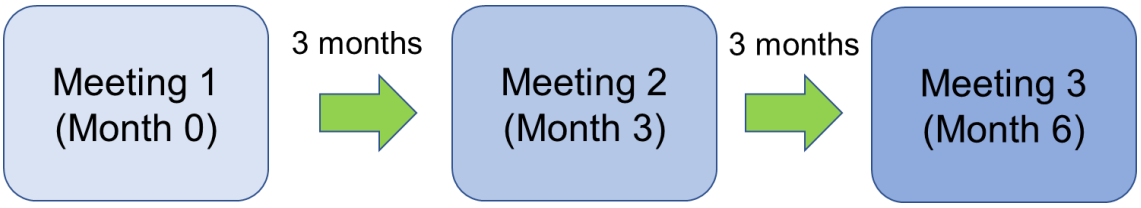


It uses technology known as Optical Coherence Tomography (OCT), which captures light that reflects off the layers of your cornea to produce a picture. Certain conditions can cause damage to these layers. Our new OCT scanner (the LiveOCT scanner) can see more detail in these layers than the regular scanners used in clinic and so help us to detect, keep track of and treat these diseases. We would like your help in this study to compare our scanner with those that are normally used in clinic.

To properly find out how well our new scanner works we need to scan 40 people with keratoconus, 30 people with Fuchs endothelial corneal dystrophy (FECD) and/ or corneal lamellar surgery, and 20 people with no diseases in their cornea. Some of these need to be children, which is where you come in.

What would I have to do if I decided to take part?

If you are interested in taking part we will arrange a time that you can talk to one of our team members so that we can tell you more and answer any questions. If, after this, you are happy to take part in the study, we will ask you to sign an assent form saying so. Your parent/ guardian will also have to sign a consent form to let us know they are happy too. We will then invite you to 3 meetings where we will carry out tests on your eyes, every 3 months, stopping at month 6.



You may have had some of these tests before if you've been for a normal eye test or tests for keratoconus or FECD at hospital. During these meetings we will also test your eyes with our new Live OCT scanner, the only test which will be new to you if you have FECD or keratoconus.

None of these tests will touch your eyes, cause pain or make you uncomfortable.

After the last test we will ask you to answer some questions about what you thought of our new scanner, for example, if it was comfortable. Our nurse can help you as much as you want with this. At the end of the questionnaire are a few questions regarding how you are feeling that day. If we are worried that you may be suffering from depression or anxiety we will forward this information onto your GP who may be able to help.

Do I have to take part?

If you decide you don't want to take part in this research, that's ok. You can decide that you don't want to take part at any time – before or after you have signed the assent/ consent form. You don't need to give a reason, and no one will be upset or annoyed. It won't affect any other treatment you get form the hospital.

What are the possible benefits of taking part?

This study will not help you directly. But what we learn from the study could help people with diseases of the cornea in future.

Could anything negative happen as a result of taking part?

All tests will be carried out by trained Doctors and Nurses and all tests (apart from our new LiveOCT scanner) are normal tests regularly carried out at the hospital. Although we cannot guarantee that there are no risks to you, we have designed and constructed our new scanner carefully to minimise any potential risks.

What will happen to the information that I give you?

We will need to use information from you for this research project.

This information will include your

- NHS number
- Initials
- Name
- Contact details
- Age
- Gender

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. We will only keep your information for 15 years, after which it will be destroyed.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- 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.

Has anyone checked that the study is safe?

The sponsors (Liverpool University Hospitals NHS Foundation Trust and the University of Liverpool) and National Research Ethics Service have checked this study to make sure that it is safe and fair. Before we started this study, we also had to prove to the Medical and Healthcare products Regulatory Agency (MHRA) that our new scanner was safe.

Questions?

If you have any questions, please ask a member of our team or email or call:

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Thank you!

Date	Version	Changes
25/03/2021	0.1	Created at the request of sponsorship committee.
27/04/2021	1.0	Approved by Sponsorship committee
27/07/21	1.1	Response to NRES comments – correction of study numbers, removal of 'friendly, and 'don't worry', response to anxiety/ depression, Dr=Doctor, storage of data and addition of contact details – **APPROVED by NRES**
25/10/2021	1.2	Change made on risks following the MHRA comments.
01/11/21	2.0	Same as version 1.2 - approved by MHRA