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. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Please don't hesitate to ask us if you would like more information or if there is anything that you do not understand. Please also feel free to discuss this with your friends, relatives and GP if you wish. We would like to stress that you do not have to accept this invitation and should only agree to take part if you want to.

Thank you for reading this.

The Study

What are we studying?

We have recently developed a scanner that allows one to see the layers of the cornea (the clear window at the front of the eye). It uses technology known as Optical Coherence Tomography (OCT), which captures light that reflects off the layers of your cornea to produce a picture. Our new OCT scanner (the LiveOCT scanner) can see more detail than the regular scanners used in clinic. We would like your help in this study to compare our scanner with those that are normally used in clinic.

The cornea is the clear window at the front of the eye and is made of many layers. Certain conditions may cause damage to these layers and lead to problems seeing clearly. We hope our LiveOCT

scanner will help us to measure these layers more accurately and so monitor and treat diseases of the cornea better.

When we study any new medical device, it is important to compare the findings with people with and without eye disease. We plan to compare our scanner to current scanners on 40 people with a condition called Keratoconus, 30 with a condition called Fuchs endothelial corneal dystrophy (FECD) and/ or corneal lamellar surgery and 20 people with no known disease in their cornea.

What would taking part involve?

If you are interested in taking part we will invite you to a meeting with the clinical research team, who will answer any questions you may have after you have read this leaflet. If you are happy to take part in the study, we will ask you to sign a consent form saying so. We will then invite you for an eye test to reveal the condition of your eye. This will include tests which you would normally receive for your eye condition or in a normal eye test (including scanning with regular OCT scanner in clinic) plus tests with our new LiveOCT scanner. We would like to ask you to come back for us to repeat these tests after 3 months and 6 months. Each appointment should last no more than 2 hours on average.

The tests are described, in order, in Table 1.

Table 1. Tests for Live OCT Study

Test	**Description**
Visual acuity test	We will ask you to read different sized letters on a chart.

Slit lamp Bio-microscopy	We will use a bio-microscope to examine your eyes by shining light into your eyes.
Endothelial Cell Counting	We will ask you to look at a target and take photographs to measure the number of cells on the back of your cornea.
Tomography	We will ask you to sit in front of a lighted bowl that contains a pattern of rings. We will take photographs to measure the shape of your eyes.
Optical Coherence Tomography	We will ask you to look at a target. The OCT scanner normally used in clinic will scan the front of your eye to produce a picture. This will be repeated with our new LiveOCT scanner.

You shouldn't feel any discomfort or changes to your vision during any of the tests and at no point will anything touch your eye. All tests, except for our new OCT scanner are part of normal tests used in clinic for people with Keratoconus/ FECD. We will also ask you to fill out a simple questionnaire about how you found being scanned with our LiveOCT scanner. You may want to fill this in by yourself but our study nurse will be around to help – she can ask and fill in the questions for you if you prefer. 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.

We will pay your costs of travel up to £20.00 for each visit (we ask that you save and give us your receipts)

What are the possible benefits of taking part?

This study will not be of direct benefit to you. Results from this study could, however, deliver benefits to the general population of those suffering with corneal and more general eye conditions in the future.

What are the possible disadvantages and risks of taking part?

All tests will be carried out by trained clinical staff and everything apart from our new LiveOCT scanner is part of normal care at St. Paul's Eye Unit, Royal Liverpool University Hospital. We have carried out careful risk assessments and safety tests on our LiveOCT scanner and it has been approved for study on humans by the relevant organisation (Medical and Healthcare products Regulatory Agency [MHRA]). None of the tests will touch your eyes. There should not be any side effects and it should not affect your insurance.

Other Information

What if I want to leave the study?

You do not have to take part in this study if you do not want to. If you choose not to take part, this will not affect the standard of any health care you receive now or in the future. If you decide to take part and then change your mind you can leave at any point without giving a reason. If you wish to leave, we will destroy all your personal information from the study. Other information collected from you up to the time of you leaving the study will be included in the study results unless you do not wish it.

In the (perhaps unlikely) event of a lack of capacity, the research team will retain personal data collected and continue to use it confidentially in connection with the purposes for which the consent is being sought. This could include further research after the current project has ended.

How will we use information about 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.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- At www.hra.nhs.uk/information-about-patients/
- our leaflet from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team or
- by sending an email legal@liverpool.ac.uk

Who has approved the study?

The sponsors (Liverpool University Hospitals NHS Foundation Trust and the University of Liverpool) and National Research Ethics Service have reviewed this study. *Note to sponsorship committee: There is pending approval by a Research Ethics Committee and the Medicines and Healthcare products Regulatory Agency (MHRA).*

If you want to talk to someone

If there is a problem, or you have questions:

Study Project Manager (Dr Sharon Mason)

sharon.mason@liverpool.ac.uk

07503343516

Department of Eye and Vision Science
University of Liverpool
William Henry Duncan (Apex) Building
6 West Derby Street
Liverpool L7 8TX

If you have a complaint or concern which you feel you cannot come to us with:

The Research Ethics and Integrity Office

ethics@liv.ac.uk and

RGT@rlbuht.nhs.uk.

When contacting the Research Ethics and Integrity Office, please provide details of the name or description of the study (so that it can be identified), the researcher(s) involved, and the details of the complaint you wish to make.

or

PALS (Patient Advice Liaison service)

0151 529 3287

PALS&Complaints@rlbuht.nhs.uk

If you have worries about your personal data:

Questions -

Study Chief Investigator (Prof Stephen Kaye)
sbkaye@liverpool.ac.uk
0151 706 3997

Complaints -

Information Commissioner's Office

0303 123 1113.

Date	Version	Changes
03.12.2020	0.1	Original document submitted to sponsorship committee
29.01.2021	0.2	Updated to the newest HRA template and resubmitted to sponsorship committee
25.03.2021	0.3	Updated requested by sponsorship committee
27.04.21	1.0	Approved by Sponsorship committee
27.07.21	1.1	Response to NRES comments – correction of study numbers, response to anxiety/ depression, loss of capacity, and storage of data