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A new high-resolution 3D imaging camera for the front of the eye

Submission date 18/10/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/10/2021	**Overall study status** Completed	
Last Edited 23/05/2025	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims
The cornea is the clear outer layer at the front of the eyeball. It acts as a window to the eye. We have invented a new higher resolution Optical Coherence Tomography (OCT) scanner which will allow us to see the layers of the cornea in more detail than is possible with scanners currently used in clinic. The scanner shines light at the cornea and then captures the light that reflects off the layers that make up the cornea to produce a cross sectional image showing a 'slice' of the cornea. We have developed 2 slightly different versions of our scanner: D1 and D2. The scanners only differ slightly in their internal optical arrangements (the way they capture and analyse the light reflected from the cornea), and the image produced, and user and patient experience will be identical.

As part of this project, we plan to test our new scanners against those already used in clinic, on participants with corneal diseases and those without any known corneal condition. We hope to demonstrate that our scanner can see the cornea in more detail than current scanners and thus would improve the diagnosis and management of these corneal diseases.

We will also obtain feedback on patient experience and compare the costs to the NHS of using the new scanner in clinic with existing scanners.

Who can participate?
Anyone 12 years old or older with a diagnosis of either Fuchs endothelial corneal dystrophy (FECD) or corneal lamellar surgery, Keratoconus, or no known corneal disease (healthy volunteers). Those with Nystagmus will be excluded.

What does this study involve?
Participants will be invited for an eye test to reveal the condition of their eyes. This will include, non invasive, tests which would normally be carried out during standard eye tests for Keratoconus and FECD (including scanning with regular OCT scanner in clinic) plus tests with our 2 new LiveOCT scanners. These tests would be repeated after 3 months and 6 months. Each appointment should last no more than 2 hours on average. Participants will also be asked to fill out a simple questionnaire about how they found being scanned with our LiveOCT scanner.

What are the possible benefits and risks of participating?
This study will not be of direct benefit to the participant. Results from this study could, however, deliver benefits to the general population of those suffering from corneal and more general eye conditions in the future.
All tests will be carried out by trained clinical staff and everything apart from the new LiveOCT scanner is part of normal care at St. Paul's Eye Unit, Royal Liverpool University Hospital. careful risk assessments and safety tests have been carried out on the LiveOCT scanner and it has been approved for study on humans by the relevant organisation (Medical and Healthcare products Regulatory Agency [MHRA]). There should not be any side effects and it should not affect your insurance.

Where is the study run from?
St. Paul's Eye Unit, Royal Liverpool University Hospital (UK)

When is the study starting and how long is it expected to run for?
May 2021 to October 2022

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Prof Stephen Kaye, sbkaye@liverpool.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Stephen Kaye

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
292051

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
IRAS 292051, CPMS 49836

Study information

Scientific Title
Clinical evaluation of a novel LiveOCT (Optical Coherence Tomography) device to improve the management of eye disease

Acronym
LiveOCT

Study objectives
The benefits of corneal ultrahigh axial resolution (<3 μm in air) (UHR) optical coherence tomography (OCT) systems have been reported using research only systems, but no such system has been made commercially available for general clinical practice. LiveOCT has been designed to fill this market niche and clinical unmet need. To evidence the clinical efficacy of this newly developed device, the following series of specific hypotheses will be tested.

The LiveOCT device reliably captures UHR OCT images of the cornea. (Note the ease of capture will be quantifiably assessed against current standard resolution OCT systems.)

The following features can be identified and resolved (in priority order)

Bowman’s layer thickness

Epithelium thickness

Total corneal thickness

Keratocytes and their density (count) in the stroma

Descemet’s membrane thickness

Post processing of the data enables automated measurement. (Note, where applicable, these measures correspond with the values returned by the comparison standard techniques and correlate with the clinical diagnosis.)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/08/2021, Yorkshire & The Humber – Leeds West Research Ethics Committee (NHSBT, Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 104 8088; leedswest.rec@hra.nhs.uk), ref: 21/YH/0132

Study design
Prospective observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Corneal diseases

Interventions
In vivonon-contact imaging of the layers of the cornea using a new anterior segmentLiveOCTimaging device. 2 slightly different variants will be used. The only differencebetween variant 1 (D1) and variant 2 (D2) will be a small modification to the internal optics with no difference to user or patient experience.

During each visit, the participant will undergo standard eye examinations (visual acuity and slit-lampbio microscopy), and non-invasive tests including endothelial cell counting (ECD), tomography, and OCT imaging by standard OCT devices(TOMEY CASIA SS-1000and HeidelbergSpectralis) and our newLiveOCTdevicevariants (D1 and D2). All apart from our novel LiveOCT device is part of standard care.

Two qualified individuals, both operating one of twoLiveOCTdevices equipped with the study software, will perform the study device measurements. Each patient will be measured three times with each device at baseline and at follow-up visits(after 3 and 6 months).

Intervention Type
Device

Phase
Phase I

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome measure
The clarity of the images produced by the OCT devices - specifically whether we can see the boundaries of the layers of the cornea such as Bowman's layer, epithelial layer, stroma, and endothelial layer, in comparison to existing OCT models (TOMEY CASIA SS-1000and HeidelbergSpectralis), measured by the device operator objectively viewing images - and recording onto CRF whether these layers are visible or not at baseline, month 3 and month 6

Secondary outcome measures

1. Repeatability/reproducibility of measurements using the LiveOCT device of structural parameters of the cornea, corneal surface contour and refractive power at baseline, month 3 and month 6. We will take 3 images for each participant, for each study visit on both of our 2 LiveOCT devices. We will compare the images (using criteria mentioned above for image quality) to assess reproducibility. For example - can you identify all the layers in every image taken?
2. Sensitivity and specificity of the LiveOCT device, using published grading systems specific to the main conditions of Fuchs Endothelial Corneal Dystrophy and keratoconus at baseline, month 3 and month 6. For keratoconus, the sensitivity of the LiveOCT will be assessed by its ability to detect the same diagnostic parameters of non-uniform and focal corneal thinning and irregular and non-asymmetric anterior and posterior corneal profiles currently measured using the Pentacam. For FECD, the sensitivity of the LiveOCT will be assessed by its ability to measure increases in corneal thickness and areas of corneal swelling, and excrescences (guttata) and thickening of Descemet's membrane in patients who have guttata evident with slit lamp bio microscopy and increased corneal thickness measured with the Pentacam. Specificity will be defined as the percentage in which the described diagnostic changes in the cornea for keratoconus and FECD are not apparent with the LiveOCT device.
3. Patient Experience of being scanned by the LiveOCT device, measured using a patient experience questionnaire to be filled in by participants at the end of each study session at baseline, month 3 and month 6.
4. Cost effectiveness of the LiveOCT device compared to existing OCT models (TOMEY CASIA SS-1000and HeidelbergSpectralis) using a cost consequences analysis using data from visits at baseline, month 3 and month 6.

Overall study start date
01/05/2021

Completion date
30/10/2022

Eligibility

Key inclusion criteria
1. Aged 12 years or above
2. Diagnosis of either Fuchs endothelial corneal dystrophy (FECD) or corneal lamellar surgery, Keratoconus, or no known corneal disease (healthy volunteers)

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
Therewill be3 groups of participants: 40 patients with keratoconus, 30 with FECD and/or corneal lamellar surgery, and20 with no known corneal abnormality.

Key exclusion criteria

1. Nystagmus
2. Inability to provide informed consent

Date of first enrolment
30/11/2021

Date of final enrolment
30/10/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clinical Eye Research Centre (CERC), St Pauls Eye Unit
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Sponsor information

Organisation
University of Liverpool

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Sponsor type
University/education

Website
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ROR
https://ror.org/04xs57h96

Organisation
Royal Liverpool and Broadgreen University Hospital NHS Trust

Sponsor details
Royal Liverpool University Hospital, Prescott street
Liverpool
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United Kingdom
L7 8XP
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RGT@rlbuht.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.rlbuht.nhs.uk/Pages/RoyalHome.aspx

ROR
https://ror.org/009sa0g06

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/01/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.
Type of data available: All of the individual participant data collected during the trial, after anonymisation would be available for request. The same data University of Liverpool have access to and control of.
Name and email: Stephen Kaye, sbkaye@liverpool.ac.uk
When available and for how long: (beginning 12 months after publication of results and ending 14 years following the completion of the study).
Access criteria: Investigators whose proposed use of the data has been approved by an independent review committee such as ethics committee (NREC or equivalent) and who provide a methodologically sound proposal.
Type of analysis: To achieve aims in the approved proposal.
What mechanism: Data are available for 15 years at The Research Data Catalogue (DataCat) of University of Liverpool website. Proposals should be directed to Stephen Kaye. To gain access, data requestors will need to sign a data access agreement. Proposals may be submitted up to 13 years after the study completion. After 36 months the data will be available without investigator support other than deposited raw data. Information regarding submitting proposals and accessing data may be found at (Link to be provided after the study completion).
Consent: yes, obtained
Data anonymisation: All data will be anonymous

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1	27/07/2021	19/11/2021	No	Yes
Participant information sheet	PIS for participants aged 12-15 years version 2.0	01/11/2021	19/11/2021	No	Yes
Participant information sheet	PIS for participants aged 16-17 years version 2.0	01/11/2021	19/11/2021	No	Yes
Protocol file	version 3	14/11/2021	19/11/2021	No	No
HRA research summary			28/06/2023	No	No
Results article		22/05/2025	23/05/2025	Yes	No