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‘iCam’ polymerase chain reaction (PCR) testing for rapid diagnosis of eye infections

Submission date 23/01/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/01/2023	**Overall study status** Completed	
Last Edited 03/02/2025	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims
Infections of the eye are a common cause of severe vision loss. Examples include infections of the clear window at the front of the eye (corneal infection) and infections in the jelly of the eye. By identifying these infections early, we are more likely to successfully treat them.

Currently, we adopt a blanket approach of treating for all infections whilst we wait for results from samples taken from the infected site. The labs grow the microbes in dishes using samples from the infected sites and visually identify them. This process takes about a week.

Our study hopes to use a quicker method much like genetic sequencing, to find which bacteria, virus or fungus is causing the infection in the eye so that we can use specific antibiotics to fight that infection. This avoids the harmful side effects of using multiple antibiotics to ‘cover’ all possible infections.

If this study is successfully shown to be better than the current practice, we hope to make this our future gold standard of care, so that patients can receive better care in the future in line with current advances in medical sciences.

Who can participate?
All patients presenting to the eye department with a corneal ulcer or infection are being invited to participate in this study.

What does the study involve?
The cornea is the clear outer layer at the front of the eyeball that acts as a window to the eye. Any injury (such as trauma or infection) can lead to scarring and loss of vision. In cases of infections, this can largely be avoided by early recognition and treatment with anti-microbials (e. g. antibiotics). In order to find the cause of the infection so that we can treat it accordingly we have to take a corneal sample or a scrape. Local eye numbing drops are put into the eye with the infection to avoid any pain and minimise any discomfort. A clean needle is used to carefully scrape the ulcer and put it into a sampling container for further testing.

Depending on the individual case, the first follow-up will be arranged 1-2 days after this procedure and then a further visit in a week and thereafter depending on the response to treatment/healing. This would not be different if they were not taking part in the study.

What are the possible benefits and risks of participating?
Taking a corneal sample (scrape) is part of routine care in cases of significant corneal ulcers. We would still need to do this procedure if the patient didn't take part in the study. The sample volume is very small and taking an additional sample for the new test has no conceivable adverse effects to the patient.
There are no anticipated disadvantages to taking part in this study or risk of harm over and above the regular care offered to patients with corneal and eye infections.
Corneal infection is a serious sight-threatening condition and we usually treat patients urgently with antibiotics (after taking a sample for laboratory testing).

It is possible that the new test is more sensitive and accurate in detecting eye infections than the current diagnostic methods. This may mean that we receive information about the bacteria, virus or fungus causing the infection earlier than normal. This should help us treat patients with more specific antibiotics avoiding any unwanted or unnecessary side effects. The doctor will discuss any treatments with the patient when making these changes to their treatment.

Where is the study run from?
Addenbrooke's Hospital, Cambridge (UK)

When is the study starting and how long is it expected to run for?
July 2021 to December 2023

Who is funding the study?
The research is being organized by Cambridge University Hospitals (CUH).
The Addenbrookes Charitable Trust has kindly agreed to fund the project.

Who is the main contact?
Mr Madhavan Rajan, madhavan.rajan1@nhs.net

Contact information

Type(s)
Principal investigator

Contact name
Prof Madhavan Rajan

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
242224

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 242224

Study information

Scientific Title
'iCam' PCR microarray for microbial diagnosis of infectious keratitis

Acronym
ICAM

Study objectives
PCR microarray is more sensitive at diagnosing microbes responsible for infectious keratitis and endophthalmitis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/07/2021, North West - Greater Manchester East Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 2071048306; gmeast.rec@hra.nhs.uk), ref: 21/NW/0238

Study design
Prospective single-centre observational cross-sectional study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Diagnosis of microbial keratitis/endophthalmitis

Interventions

Corneal scrapes or vitreous biopsies are taken from patients after instillation of topical anaesthetic eye drops (e.g. proxymetacaine/tetraine) with sterile needles/blades and placed in a transport medium. This is then sent to the department of clinical microbiology, Public Health England Laboratory at Addenbrookes and PCR microarray is performed on the sample. Samples may be frozen until sufficient samples have been collected for a single array card. The result can then be compared to the sample sent for bacterial/fungal microscopy, culture and sensitivity as per the current standard of care.

Intervention Type
Mixed

Primary outcome(s)
Microbial detection using PCR and conventional culture techniques. The measure is the positive identification of the microbe in the suspected cases of ocular infection. Measured at a single time point.

Key secondary outcome(s))
Ct values (threshold cycle) at time of running array card.

Completion date
31/12/2023

Eligibility

Key inclusion criteria
All patients, aged 18 years and above, presenting to eye department with a corneal ulcer or suspected endophthalmitis

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
36

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment

22/09/2021

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Addenbrookes
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Charity

Funder Name
Addenbrookes Charitable Trust

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and analysed from this study will be available upon request from Mr Madhavan Rajan, PI and Consultant Ophthalmologist, Cambridge University Hospitals, Cambridge UK, madhavan.rajan1@nhs.net

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/12/2024	03/02/2025	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version 1	14/06/2020	26/01/2023	No	Yes