

# 'iCam' polymerase chain reaction (PCR) testing for rapid diagnosis of eye infections

<b>Submission date</b> 23/01/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/01/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/02/2025	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data

## 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

### ORCID ID

<https://orcid.org/0000-0003-2223-5364>

### Contact details

Dept of Ophthalmology

BOX 41

Cambridge University Hospitals

Cambridge

United Kingdom

CB2 0QQ

+44 1223 216500  
madhavan.rajani@nhs.net

## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Integrated Research Application System (IRAS)**  
242224

**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?
<a href="#">Results article</a>		11/12/2024	03/02/2025	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	version 1	14/06/2020	26/01/2023	No	Yes