

'iCam' PCR microarray for microbial diagnosis of infectious keratitis – Patient Information

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This research is being organised by Cambridge University Hospitals. “We” refers to the ophthalmology team at Cambridge University Hospitals.

What is the Purpose of the study?

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 genetically sequencing, to find which bacteria, virus or fungus is causing the infection in your 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 including yourself, can receive better care in the future in line with current advances in medical sciences.

Why have I been invited to take part?

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

Do I have to take part?

No - It is up to you to decide to join the study.

We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. With your consent, your participation in the study and the relevant information will be shared with your GP.

You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

A brief explanation of the procedure

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 infection so that we can treat 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.

Follow up Arrangement

Depending on the your 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 your response to treatment/healing. This would not be different if you were not taking part in the study.

Risks of procedure

Taking a corneal sample (scrape) is part of the routine care in cases of significant corneal ulcers. We would still need to do this procedure if you 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 you.

What will I have to do?

We require your consent to use the eye samples for the additional tests intended as part of this research study.

The doctor who sees you first (normally emergency eye clinic) will explain the procedure (as we would normally) and take you through the consent form so you can ask any questions if you have at the time. If you are happy to consent at the time, we will ask you to sign the form and an additional sample will be taken from the cornea for the study.

We will follow you up as normal and will inform you of the test results at your next visit.

What are the disadvantages and risks?

There are no anticipated disadvantages by 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 normally treat you urgently with antibiotics (after taking a sample for the laboratory testing).

What are the possible benefits?

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 your infection earlier than normal. This should help us treat you with more specific antibiotics avoiding any unwanted or unnecessary side effects. Your doctor will discuss any treatments with you when making these changes to your treatment.

Will my taking part in the study be kept confidential?

All information collected about you during the course of the study will be kept strictly confidential. All data will be anonymized and securely stored on an NHS computer. Any published information will not have recognizable information about you.

Who is organizing and funding the research?

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

What if I don't want to take part in the study or if I lose the mental capacity to retain information?

At any point should you decide to leave the study, we will take you off the study. This will not affect your clinical care in any way. Your data till the point of your consent in the trial will be used for research analysis.

Should you lose the mental capacity to make decisions and retain information, you will not be required to continue in the study, without having any effect on the clinical care. We will still use the data collected till the point of exclusion for our research analysis.

Who has reviewed the study?

This research study has been reviewed by the Health Research Authority's [NRES Committee] Research Ethics Committee, which is a committee whose task is to make sure that research subjects are protected from harm.

What if I am not happy with my care or something goes wrong?

We will try our best to explain everything to you at every stage. Still, if there is any concern that you would like to raise, then please do not hesitate to contact the research team. If you are not happy or worried about your care and would like to raise a question, you can also approach the **PALS** team who are based at level 2 at Addenbrookes hospital reception or

call them at 01223-216756. If you are admitted in the hospital you can use the phone by your bed and dial *801. You can also email them at pals@addenbrookes.nhs.uk.

In case of emergency or for further details please contact us at:

Should you require more information about the study, please don't hesitate to contact the chief investigator, **Mr. Madhavan Rajan**, Consultant Ophthalmic Surgeon, Addenbrooke's Hospital, Hills Road, Cambridge, CB2 0QQ.

Telephone (Mon to Fri between 9am to 5pm): **01223-216500**

Out of Hours (after 5pm) or at weekends:

Call Addenbrooke's Hospital switchboard at **01223-245151** and ask to be connected to the Corneal Nurse, who will advise you the further.

If you would like this information in ***larger*** font or in any other format, then please do not hesitate to ask.

How do we manage patient information?

In this research study we will use information from you and your GP records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study we will save some of the data for future research.

We will make sure no-one can work out who you are from the reports we write.

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, only if that's agreeable to you.

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

You can find out more about how we use your information

- by asking one of the research team
- by sending an email to cambridgeeyeresearchcentre@addenbrookes.nhs.uk
- by ringing us on 01223 586526