Translational
Healthcare Technologies

Optical Technologies for the Detection of Respiratory Infection in the Intensive Care Unit.

Study Summary Information Sheet
BAC2BAC Study 1

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Document Control Sheet

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Senior Research Nurse	NHS Lothian	Katie Hamilton	DocuSigned by: Katie Hamilton 8BE60725CE2D405... 29-May-2025 | 20:13 BST
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Document Approval

Role	Organization	Name	Signature and Date
Interim Quality Manager (Senior Clinical Project Manager)	University of Edinburgh	Joanne Mair	Signed by: FA1FBB0991BC490... 29-May-2025 | 16:56 BST
Chief Investigator	University of Edinburgh/ NHS Lothian	Kev Dhaliwal	DocuSigned by: Kev Dhaliwal 3109A1D1316E485... 29-May-2025 | 16:50 BST

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BAC2BAC Study 1 Summary Information Sheet

This study will help to improve the way we currently sample lungs to understand what is happening when patients on ventilators have suspected or confirmed lung infection. Often, changes seen on a patient's x-ray are not clear indications of whether a patient has an infection, or what type of infection they have. Knowing this in the future will help doctors give the right treatment at the right time.

During a routine bronchoscopy procedure, which is a procedure to examine the lungs in more detail, the research team will pass a very fine microscope into regions of the lungs and deliver small volumes of liquid imaging agents (called Smartprobes) which 'light up' when they come into contact with specific bacteria or immune cells (see Figure 1 below). We will compare the results we get with methods currently used by doctors that take longer to provide results. The results of this study will not influence the treatment given. In the future, we hope that this technology can be used by health care organisations as a new method to diagnose and manage suspected lung infections.

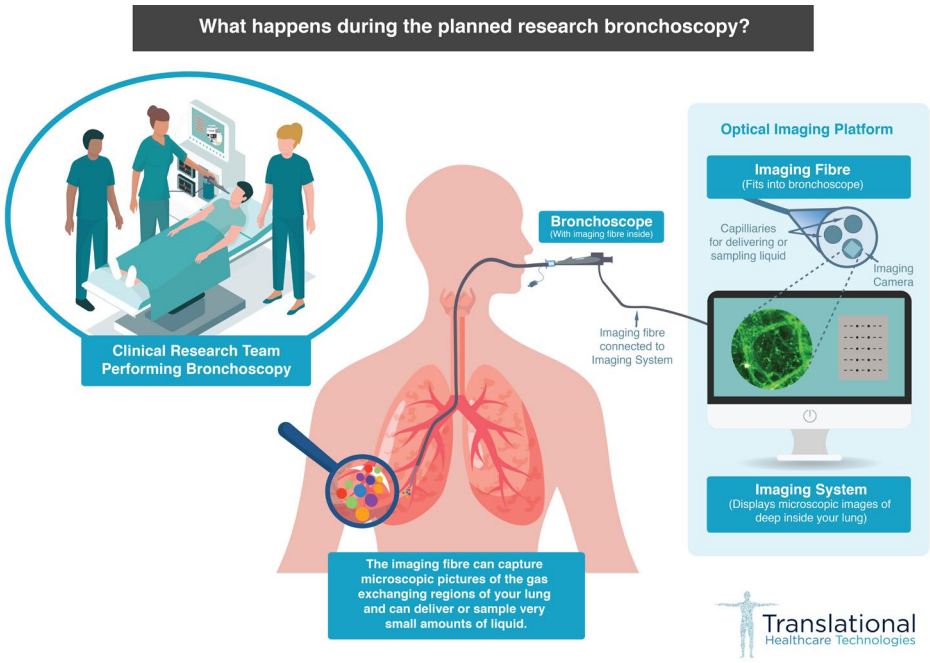

Figure 1: Bronchoscopy procedure with imaging fibre, imaging system and Smartprobes.

The imaging system (Kronoscan) and 2 of the Smartprobes have been used in a clinical study before and we have not seen any safety concerns to date. The imaging fibre (Eyes on Target) and BAC3 (Smartprobe) have not previously been used in the clinical setting but have undergone extensive pre-clinical (lab) testing.

We do not anticipate any adverse reactions to the Smartprobes that will be used in this study - only a very small amount of the Smartprobe will be used (also known as a microdose) and we have conducted extensive testing to demonstrate their safety for use in humans.

The research team would like to take an additional blood sample (up to approximately 4 teaspoons), a very small amount of lung fluid from the deeper parts of the lung (less than 5 mL) and a swab from the breathing tube before the procedure. We may also ask to take a swab from the nose from certain patients and this is optional. The research team will monitor the patient for 48 hours after the bronchoscopy and collect information regarding their health, details about their ICU stay and discharge details. A snapshot of this study can be found in Figure 2 below.

This study is led by Professor Kev Dhaliwal at the University of Edinburgh and will take place in the ICU at the Royal Infirmary of Edinburgh.

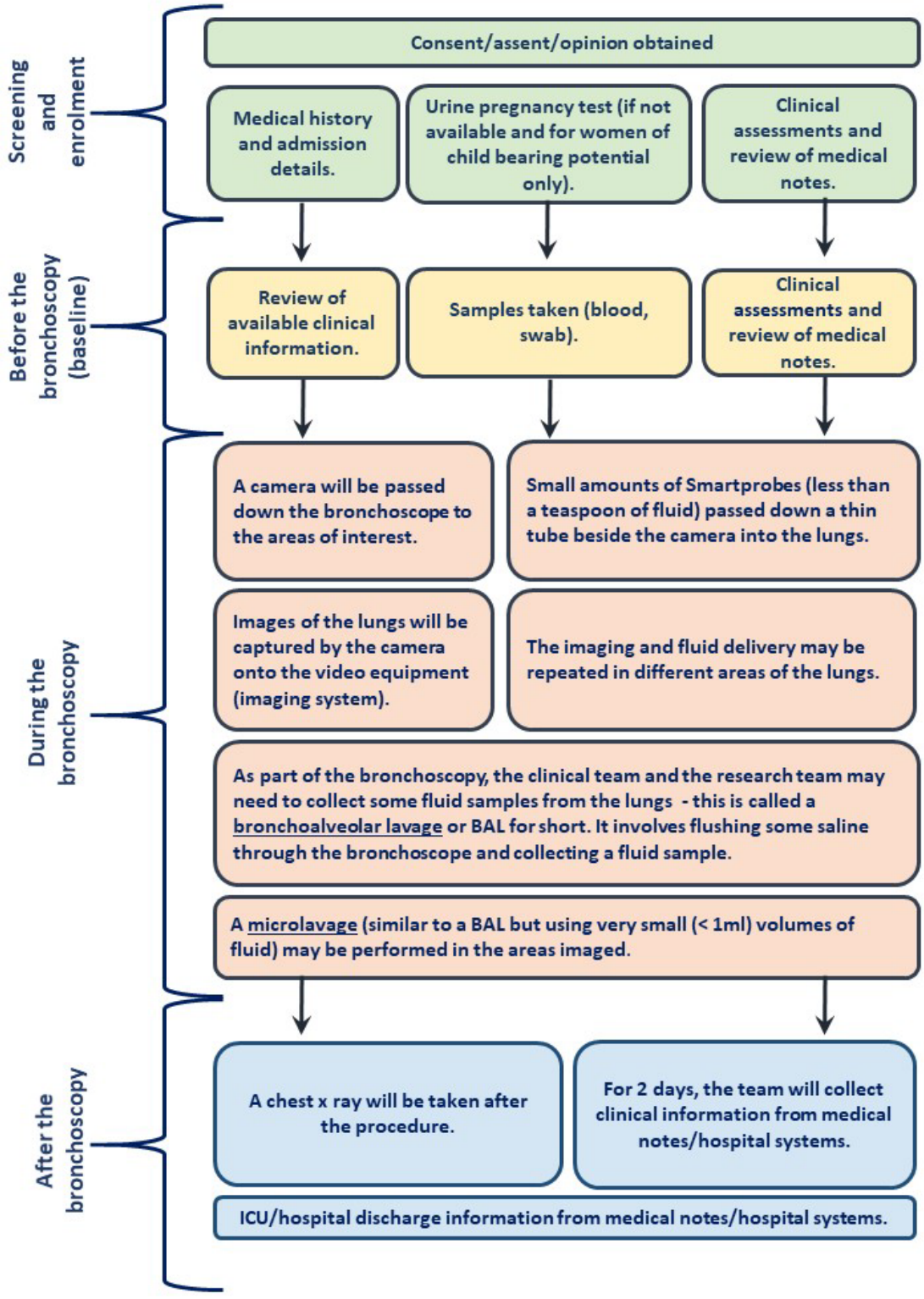

***Figure 2**: Summary of research involvement*

If you would like to hear more about this study, please speak to a member of the BAC2BAC research team (on the ward or via BAC2BAC@ed.ac.uk or with your clinical care team. We will provide you with further information and can discuss any questions you may have.