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# LungSpy - Identifying lung disease by using novel imaging techniques

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 08/03/2022 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 11/04/2022 | Ongoing | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 24/03/2025 | Respiratory | |

## Plain English summary of protocol

Background and study aims
When trying to identify lung diseases the current methods used only provide a snapshot of what is occurring in the lung. By using new technologies we hope to be able to characterise what is happening deep in the lung in order to provide new ways of diagnosing and treating lung disease. In the LungSpy study we hope to be able to develop and test novel technologies to be able to characterise disease deep in the lung. The technology includes tiny cameras that can reach far into the lung and can also deliver small volumes of fluid, called Smartprobes, which light up when they come into contact with cells that signify lung disease. Our imaging systems attach to the camera to allow these images to be viewed.

Who can participate?
We aim to recruit up to 80 participants with a variety of lung conditions. Participants must be aged over 16, have capacity to provide informed consent, deemed suitable for bronchoscopy and study procedures by attending consultant (including consideration of routine medical interventions) and they must be undergoing a clinically indicated bronchoscopy or agree to undergo a research only bronchoscopy for the purpose of the study.

What does the study involve?
Eligibility screening involves a chest x-ray, a cardio respiratory examination and baseline clinical observations including, pulse, blood pressure, temperature and oxygen saturations.

The bronchoscope will be navigated into the lungs and a camera will be passed down the bronchoscope to the areas of interest. Small amounts of Smartprobes (less than a teaspoon of fluid) passed down a thin tube beside the camera into the lungs. Images of the lungs will be captured by the camera onto the video equipment (imaging system) The imaging and fluid delivery may be repeated in different areas of the lungs . As part of the bronchoscopy, the clinical team and the research team may need to collect some fluid samples from the lungs - this is called a bronchoalveolar lavage or BAL for short. It involves flushing some saline through the bronchoscope and collecting a fluid sample.

After the procedure, routine clinical observations will be recorded and participants may require a chest x-ray before being discharged home. 24 hours after the procedure, a member of the research team may contact the participant to check how they are.

What are the potential benefits and risks of participating?
We are testing these new imaging technologies to see if they can help clinicians distinguish between healthy and diseased lung tissue. The information we gain from this study will help us improve our understanding of lung disease and inform future development of the systems.

This is the first time that the imaging fibre (camera) has been used in humans. It has been tested extensively in the laboratory to image lung cancer, infection and inflammation. The imaging fibre comes into direct contact with the lung, therefore prior to being tested in humans, it has undergone rigorous safety testing to ensure that the materials used will not cause any harm. The imaging fibre will only be operated by a qualified member of the research team.

The imaging systems (video equipment) will not come into direct contact with the participant. There are two possible systems that can be utilised during the study. This is the first time one of the systems has been used in humans. The other system has been tested in two previous human research studies. Both systems have undergone all the required testing to ensure they are safe for use and will only be operated by qualified members of the research team.

We do not anticipate any adverse reactions to the Smartprobes that may 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 toxicology studies to demonstrate their safety for use in humans. Two out of the three Smartprobes have already been tested in humans and no side effects were experienced. If, however, an unexpected reaction was to occur, all of the necessary treatments are available in the hospital.

The risks of bronchoscopy are very low, with complications occurring in less than 1-2% of procedures. The main risk is air becoming trapped next to the lung which may require a chest drain. This is extremely rare. In addition, people can commonly experience cough, fever and sore throats within 24 hours following bronchoscopy.

Participants may have two chest x-rays (one before and one after the bronchoscopy). These procedures use ionising radiation to form images of your body and provide your doctor with clinical information. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous. We are all at risk of developing cancer during our lifetime. The normal risk is that this will happen to about 50% of people at some point in their life. Taking part in this study will add only a very small chance of this happening. The radiation exposure associated with these two additional x-rays is equivalent to approximately 7 days natural background radiation in the UK.

Where is the study run from?
The study is being run from the Royal Infirmary of Edinburgh (UK)

When is the study starting and how long is it expected to run for?
January 2021 to April 2027

Who is funding the study?
Wellcome Trust (UK)

UK Research and Innovation (UK)
Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (UK)
Engineering and Physical Sciences Research Council (UK)

Who is the main contact?
Mrs Joanne Mair, j.mair@ed.ac.uk

# Contact information

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# Additional identifiers

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

### Integrated Research Application System (IRAS)
278327

### Protocol serial number
AC18083, IRAS 278327

# Study information

### Scientific Title
Probing molecular signatures in human lung disease using novel optical technologies; Lung Spy

### Acronym
LungSpy

### Study objectives
Interventional fibre-based microendoscopy is safe, feasible and demonstrates early proof-of-concept. We will evaluate a suite of novel technologies to characterise tissues in the lung. We will evaluate technologies as part of platform trial with different imaging and spectroscopy systems. chemical sensors and fibre devices.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 07/10/2021, West Midlands - Edgbaston Research Ethics Committee (3rd Floor Barlow House, Minshull Street, Manchester, M1 3DZ, UK; +44 207 104 8070; edgbaston.rec@hra.nhs.uk), ref: 21/WM/0199

### Study design
Single centre observational cohort study

### Primary study design

Observational

## Study type(s)
Other

## Health condition(s) or problem(s) studied
Lung disease including infection inflammation and cancer

## Interventions
Participants will undergo a bronchoscopy. A camera will be passed down the bronchoscope to the areas of interest. Small amounts of Smartprobes may be passed down the bronchoscope into the lungs. Images will be captured by the camera onto the imaging system. Patricipants may also have avleolar fluid sampled and biopsies undertaken.

A maximum of 2 chest x-rays will be performed (pre and post procedure)

## Intervention Type
Device

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
bronchoscopy

## Primary outcome(s)
Feasibility outcomes:
1. Completion of the research element of the bronchoscopy procedure utilising the technology (yes/no)
2. The imaging fibre reaches and is navigated to areas of interest in the lung (yes/no)
3. Imaging fibre delivers small volumes of liquids to areas of interest in the lung (Smartprobes and/or saline) (yes/no)

Safety assessed using routine clinical observations:
4. Pre-and post-procedure pulse, temperature, BP and cardiorespiratory exam.
5. O2 saturation during bronchoscopy procedure
6. Pre discharge (from bronchoscopy) BP, temp and pulse
7. Recording adverse events that occur up to 4 hours post procedure (pre discharge) and 24 hours post procedure.
8. Safety reporting for the medical devices

## Key secondary outcome(s))
Measured at the time of procedure unless otherwise noted:
1. Delivery of SmartProbes will be assessed by the fluid leaving the syringe attached to the imaging fibre.
2. FLIM signatures obtained during visualisation of suspected cancerous tissue will be compared with clinical pathology results from the patient's resected tissue and ex vivo imaging of the resected lung tissue. Images obtained demonstrating bacterial presence and inflammatory signatures will be compared with the participants suspected pathology.
3. Safety of the procedure will be assessed by routine clinical monitoring – and recording any adverse events that occur during and/or post-procedure (up to 1 hour post procedure) and pre

discharge (up to 4 hours post procedure).
4. The ability to perform a distal microlavage will be measured by the retrieval of a sufficient volume of Alveolar lavage to perform PCR. The lavage sample results will be compared to the appropriate SmartProbe signature.

### Completion date
01/04/2027

## Eligibility

### Key inclusion criteria
1. Aged ≥ 16 years
2. Deemed suitable for bronchoscopy and study procedures by attending consultant (including consideration of routine medical interventions)
3. Capacity to provide informed consent
4. Readily accessible target areas with bronchoscopy (or navigational bronchoscopy where clinically indicated) and fibre based endoscopy
5. Complies with sponsor co-enrolment criteria
6. Undergoing a clinically indicated bronchoscopy or agrees to undergo a research only bronchoscopy for the purpose of the study

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
16 years

### Sex
All

### Key exclusion criteria
1. History of anaphylaxis
2. Documented history of allergy to fluorescein
3. Women (of childbearing potential) who are pregnant or are breastfeeding
4. Currently prescribed drugs that cause increased autofluorescence in the lung, specifically amiodarone and methotrexate

### Date of first enrolment
01/04/2022

### Date of final enrolment
21/07/2022

## Locations

**Countries of recruitment**
United Kingdom

Scotland

**Study participating centre**
**Royal Infirmary of Edinburgh**
51 Little France Crescent
Old Dalkeith Road
Edinburgh
United Kingdom
EH16 4SA

# Sponsor information

**Organisation**
University of Edinburgh

**ROR**
https://ror.org/01nrxwf90

**Organisation**
NHS Lothian

**ROR**
https://ror.org/03q82t418

# Funder(s)

**Funder type**
Charity

**Funder Name**
Wellcome Trust

**Alternative Name(s)**
Wellcome, WT

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**
Trusts, charities, foundations (both public and private)

**Location**
United Kingdom

**Funder Name**
UK Research and Innovation

**Alternative Name(s)**
UKRI

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

**Funder Name**
Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator

**Alternative Name(s)**
Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator, CARB-X

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
International organizations

**Location**
United States of America

**Funder Name**
Engineering and Physical Sciences Research Council

**Alternative Name(s)**

UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, Science Research Council, Science and Engineering Research Council, EPSRC, SRC, SERC

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

# Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request from the study team following completion of the study.
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### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Basic results | | 20/03/2025 | 21/03/2025 | No | No |
| HRA research summary | | | 26/07/2023 | No | No |
| Participant information sheet | version 1.0 | 11/06/2021 | 16/03/2022 | No | Yes |