

LungSpy - Identifying lung disease by using novel imaging techniques

Submission date 08/03/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/04/2022	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/03/2025	Condition category Respiratory	<input type="checkbox"/> Individual participant data

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?
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Additional identifiers

Integrated Research Application System (IRAS)
278327

Protocol serial number
AC18083

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. Participants may also have alveolar 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 \geq 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/01nrxf90>

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