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Identifying lung disease by using novel imaging techniques

Submission date
08/08/2025

Recruitment status
Not yet recruiting

Registration date
21/08/2025

Overall study status
Ongoing

Last Edited
19/08/2025

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
When someone has symptoms that indicate a potential lung condition, a doctor will often request a scan of the lungs. Should the doctor spot something on the scan that needs further investigation, like a mass or a build-up of fluid, a bronchoscopy is usually required.
However, a major limitation of bronchoscopies is that the smallest bronchoscope devices (3 mm diameter) are too wide to access the narrower parts of the lung. If the suspected mass is in a narrower part of the lung, the bronchoscopist must try to obtain a sample without visualisation of the target. This can result in being uncertain as to what they have sampled, or instead sampling healthy tissue that is near the suspected abnormal tissue.
Precision Lung aims to test the safety and feasibility of two new imaging technologies that are used together, during a standard clinical bronchoscopy, to allow doctors to see deep inside the lungs and facilitate sampling in deeper, harder-to-reach areas of the lung.
The new technologies are an imaging device called Eyes on Target (EoT), which has a miniaturised fibre-optic camera and a 1.2 mm working channel. This is no larger than the fibre that would be used clinically. The EoT fibre connects to and works with a new imaging system called KronoScan.

Who can participate?
Anyone over the age of 16 years who has a suspected or confirmed lung malignancy and is undergoing a clinically indicated bronchoscopy and deemed suitable for study procedures by the attending consultant (including consideration of routine medical interventions). They must also have the capacity to provide informed consent.

What does the study involve?
After informed consent is obtained, the research team will confirm that the participant is eligible to take part in the study by looking at their medical records, obtaining a urine sample for a pregnancy test if the participant is of child bearing potential, review the results of a CT scan (within 3 months of the day of the bronchoscopy) and review relevant medical history.
If eligible, the research team will conduct a cardiorespiratory exam and check vital signs (heart rate, blood pressure, temperature, O2 saturations, and respiratory rate) of the participant before the bronchoscopy procedure.
The research part of the bronchoscopy will be performed during the clinically indicated

bronchoscopy. As part of the standard bronchoscopy, the participant will be sedated and the bronchoscope (a thin tube with a camera at the end) is passed down through the mouth into the lungs. The EoT imaging fibre will then be guided down the inside of the bronchoscope to image deep inside the lungs.
These images will be displayed on the KronoScan imaging system.
After imaging is complete, a number of very small samples will be taken from the area(s) of the lung where the suspected disease is, using routinely used, clinically approved tools. These samples may be taken whilst the EoT imaging device remains inside the bronchoscope, and/or once it has been removed. The types and volume of samples taken will be decided by the clinician according to what they deem to be the most appropriate to provide a diagnosis. All samples that are taken during the bronchoscopy procedure will be sent to the NHS Lothian pathology laboratory. The devices do not provide a diagnosis, but instead help in the collection of samples that will be used by NHS Lothian to provide a diagnosis.
A standard bronchoscopy procedure takes approximately 25-30 minutes to perform. The research procedure may lengthen the bronchoscopy procedure by up to 25 minutes.
Post-bronchoscopy care and discharge (home or back to the ward) will be done in accordance with standard clinical practice and under the direction of the participant's clinical doctor. This includes carrying out a chest X-ray up to four hours post-bronchoscopy.
At 1 hour post-bronchoscopy, a clinically trained and delegated member of the research team will record the participant's pulse, blood pressure, temperature, and respiratory rate (clinical observations), if not completed as part of standard clinical care. This is repeated four hours post-bronchoscopy alongside a cardiorespiratory assessment. The cardiorespiratory assessment is additional to standard care.
If the participant is an inpatient, there will be a follow-up ward visit at 24 hours and 7 days after the bronchoscopy procedure. If they are an outpatient, these two follow-up visits will be conducted over the phone. Both follow-up visits will assess whether the participant has had any adverse events following the bronchoscopy.

What are the possible benefits and risks of participating?
While there are no direct benefits to taking part, we are testing these new imaging technologies to see if they can help doctors distinguish between healthy and diseased lung tissue in order to take a more accurate tissue sample (biopsy) in the future. It is hoped that these technologies will accelerate the time taken to reach an accurate diagnosis, thereby informing treatment plans and transforming patient management and care.
The imaging system (KronoScan) has been used in a clinical study before and we have not seen any safety concerns to date. The imaging fibre (EoT) has not previously been used in a clinical setting but has undergone extensive pre-clinical (lab) testing.
As the participant will already be having a bronchoscopy as part of their standard clinical care, the risks associated with a bronchoscopy procedure are not affected by this study. These risks will be discussed with the participant by their clinical doctor as part of their standard clinical care.

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

When is the study starting and how long is it expected to run for?:
September 2023 to January 2026

Who is funding the study?
Prothea Technologies (UK)

Who is the main contact?
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Contact information

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Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
345499

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Sponsor Ref: AC24150

Study information

Scientific Title
Safety and feasibility of a novel device system for tissue visualisation and characterisation

Acronym
Precision Lung

Study objectives
To demonstrate feasibility and safety of KronoScan and Eyes on Target (EoT) in participants undergoing a clinically indicated bronchoscopy

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/08/2025, South East Scotland Research Ethics Committee 2 (Mainpoint, 102 West Port, Edinburgh, EH3 9DN, United Kingdom; +44 (0)7814 764 241; Ruth.Fraser4@nhslothian.scot.nhs.uk), ref: 25/SS/0052

Study design
Single-centre interventional cross-sectional cohort study and clinical investigation of medical devices

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Safety, Efficacy

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Lung cancer

Interventions
As this is a non-randomised, early-stage medical device investigation, a control/placebo group has not been included.

Non-clinical interventions:
1. Informed consent: taken once per participant by an appropriately delegated member of the research team, taking an average of 30 minutes.
2. Review of clinical notes: taken eight times per participant by a qualified member of the research team, taking an average of 10 minutes.
3. Review and confirmation of eligibility: completed by an appropriately delegated member of the research team (to be repeated if screening and bronchoscopy are on different days).
4. Clinical user questionnaire informed consent: taken once per clinician who will be trained to use/operate the imaging technologies by an appropriately delegated member of the team.
5. Clinical user questionnaire completion: one completed per participant by the clinician who conducted the clinical bronchoscopy and research procedure. Captures usability and performance feedback about the imaging technologies (investigational devices).

Clinical interventions:
1. Medical history: taken once per participant by a qualified member of the research team, taking an average of 10 minutes.
2. Pregnancy test: taken once per participant if they are of childbearing potential, by a qualified member of the team, taking an average of 5 minutes.
3. Clinical bronchoscopy: conducted by a medically qualified member of the research team, taking an average of 25 minutes (not including the research procedure).
4. Investigational device research procedure (during bronchoscopy): conducted by a medically qualified member of the research team, involving imaging and sampling of lung tissue (using the KronoScan and Eyes on Target devices in accordance with the clinical investigational protocol). This will take a maximum of 25 minutes (in addition to the clinical bronchoscopy).
5. Cardiorespiratory examination: taken by a qualified member of the research team once before the procedure and once up to four hours after the procedure. Each examination takes an average of 10 minutes.
6. Check of vital signs (heart rate, blood pressure, temperature, O2 saturation, and respiratory rate): taken by a medically qualified member of the research team, once before the procedure, once up to an hour after the procedure, and once up to four hours after the procedure. The average time per check is 10 minutes.
7. Check of vital signs (heart rate and O2 saturations only): taken by a medically qualified member of the research team during the bronchoscopy procedure as part of standard clinical practice. Taking an average of 5 minutes.

8. Adverse events: events that occur from the time of consent up until discharge from the study will be recorded at enrolment (post-consent), pre-bronchoscopy, during bronchoscopy, 1 hour post-bronchoscopy, 4 hours post-bronchoscopy, 24 hours and 7 days post-bronchoscopy.
9. Device deficiencies: These will be assessed at the time of the bronchoscopy procedure.
10. Chest X-ray: Taken once, by a medically qualified member of the research team, as part of standard clinical practice, up to 4 hours post-bronchoscopy procedure (not considered a deviation from protocol if taken >8 hours post-bronchoscopy).

This study encompasses the following technologies:
KronoScan - an imaging unit that utilises optical scanning for both fluorescence intensity and fluorescence lifetime imaging. This is a non-invasive medical device as it does not come in direct contact with the participant.
Eyes on Target (EoT) - an imaging fibre that will be inserted down a compatible commercial bronchoscope and used to image and sample the internal microstructure of the lung. This is an invasive medical device.

All sampling for participants will be EoT navigated, but some samples may also be EoT directed
EoT-directed sampling refers to samples obtained directly via the working channel of EoT using compatible (UKCA/CE-marked) biopsy tools.
EoT-navigated sampling refers to using the EoT device to navigate to the area of interest, then withdrawing EoT from the navigation catheter to allow deployment of standard clinical tools to be used to obtain samples (i.e. these tools are not deployed down the EoT working channel).

The decision whether a sample will be EoT directed will be a clinical decision based upon the participant's presenting diagnosis and the anticipated pathology.

Participants will include in-patients or out-patients who will undergo clinically indicated bronchoscopy for suspicious nodules and/or suspected or confirmed cancer based on CT scan results from within the last 3 months.

All participants will be scheduled for a clinically indicated bronchoscopy (for further investigation /biopsy) and the research element of the procedure will take place at the same time.

There is no requirement for a time delay between consecutive participants and it is permissible for more than one participant to be consented and imaged on the same day.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Eyes on Target (EoT1), KronoScan (KC.02)

Primary outcome measure
Feasibility of devices (KronoScan and EoT) will be assessed by:
1. The acquisition of cancer and non-cancer imaging data (with a minimum of 30 frames, at a rate

of at least 2.8 frames per second) per area imaged during a clinically indicated bronchoscopy procedure at the time of image analysis (after the bronchoscopy procedure).

Safety of the devices will be assessed by:
1. The number of adverse events that occur, assessed at the following timepoints: enrolment (post-consent), pre-bronchoscopy, during bronchoscopy, 1 hour post-bronchoscopy, 4 hours post-bronchoscopy, 24 hours and 7 days post-bronchoscopy
2. The number of device deficiencies that occur, assessed during the bronchoscopy
3. Routine clinical monitoring methods including:
3.1. Cardiorespiratory examinations assessed pre-bronchoscopy and 4 hours post-bronchoscopy
3.2. Chest X-ray or computed tomography (CT) scan assessed at screening and enrolment (based on any results done previously as part of clinical care that are within 3 months of the date of bronchoscopy) and again at 4 hours post-bronchoscopy as part of clinical care. (However, it will not be considered a deviation if done >8 hours post-bronchoscopy).

Secondary outcome measures
1. The ability to obtain in vivo fluorescence lifetime metabolic signatures in cancerous and non-cancerous lesions will be measured using imaging data of suspected cancerous vs control areas taken during the bronchoscopy. The imaging data will then be correlated with the signatures reported with the pathology results from samples taken during the bronchoscopy.
2. The capability of EoT to sample or facilitate sampling of tissue for the assessment of lung pathologies will be measured using samples obtained during the bronchoscopy and the pathologist's report on the quality and volume of these samples for making a pathological assessment.

Overall study start date
12/09/2023

Completion date
31/01/2026

Eligibility

Key inclusion criteria
1. ≥16 years old
2. Suspected or confirmed lung malignancy
3. Undergoing a clinically indicated bronchoscopy and deemed suitable for study procedures by the attending consultant (including consideration of routine medical interventions)
4. Capacity to provide informed consent
5. Complies with co-enrolment criteria as outlined in Clinical Protocol (section 6.4.9)

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex

Both

Target number of participants
30

Key exclusion criteria
1. Currently pregnant
2. Unlikely to tolerate the bronchoscopy study procedure in the opinion of the attending clinician or operator
3. Currently receiving long-term oxygen therapy or ambulatory therapy

Date of first enrolment
12/09/2025

Date of final enrolment
21/01/2026

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Royal Infirmary of Edinburgh at Little France
51 Little France Crescent
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Sponsor information

Organisation
University of Edinburgh & Lothian Health Board ACCORD

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Sponsor type
University/education

Website
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Funder(s)

Funder type
Industry

Funder Name
Prothea Technologies Ltd

Results and Publications

Publication and dissemination plan
The Clinical Investigation/Performance Study Report (CISR/CPSR) will be submitted to the Co-Sponsors and REC within 1 year of the end of the study. The Chief Investigator will provide the Report to ACCORD for review prior to finalization. The clinical investigation/performance study report may be used for publication and presentation at scientific meetings. Investigators have the right to publish orally or in writing the results of the study. The results of the study, together with other mandated information, will be uploaded to the European clinical trials database within 1 year of the end of the study.

Summaries of results will also be made available to Investigators for dissemination within their clinics (where appropriate and according to their discretion).

A summary of the results will be uploaded to ISRCTN.

Intention to publish date
31/01/2027

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	25/07/2025	19/08/2025	No	Yes