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iDx Lung Health – Developing new tests for the early detection of lung cancer

Submission date 05/01/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 03/02/2021	**Overall study status** Ongoing	
Last Edited 11/10/2024	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-using-blood-samples-and-a-nose-swab-to-detect-lung-cancer-idx-lung

Background and study aims
Lung cancer is the most common cause of cancer-related death worldwide. Survival rates are poor and survival rates over 10 years have not changed over the past 40 years. The majority of patients currently receive a cancer diagnosis once the cancer is in an advanced stage and treatment is not possible. Attempts to improve survival rates in lung cancer are now focussed on early diagnosis and screening. Following a successful pilot study in Manchester, NHS England is rolling out an extended Lung Health Check (scan of the lungs) pilot across 10 sites, including Southampton & Leeds. From mid-2020, a scan will be offered to people between the ages of 55-75 who have ever been smokers.
The aim of this study is to find out whether studying samples of blood or tissue from inside the nose of these patients attending a routine Lung Health Check can help doctors to develop tests to detect lung cancers quicker, leading to faster diagnosis and more effective treatment.

Who can participate?
The researchers are inviting everyone who is having a Lung Health Check in Southampton or Yorkshire to consider taking part. In Southampton patients will be able to take part whether they are referred for a CT scan or not. In Yorkshire they will be able to take part if they are referred for a CT scan.

What does the study involve?
Once participants have signed a consent form online they will undergo a routine Lung Health Check triage test and will either have a low dose CT scan or not as part of the Lung Health Check programme. The study will involve donating a blood sample and a soft brush sample from the nose at the same time as the Lung Health Check. Participants will not be required to attend any further visits for the study.

What are the possible benefits and risks of participating?
It is hoped that this study will improve the Lung Health Check for people in the future by detecting lung cancer earlier. It is uncertain whether this will help patients directly now, but it

may help many others in the future. One of the blood tests may suggest there might be something that needs further investigation. If this is the case, the result will be passed on to the Lung Health Checks team so that they can decide whether enrolled subjects need any more tests. There will be no greater risk than a routine blood test. The taking of blood may sometimes cause discomfort or bruising in the skin and tissue around the vein where blood is taken. Taking a soft brush sample from the nose can cause minimal discomfort. Both will be undertaken by a trained health care professional to minimise any risk.

Where is the study run from?
University of Southampton Clinical Trials Unit (SCTU) (UK)

When is the study starting and how long is it expected to run for?
November 2020 to January 2027

Who is funding the study?
Innovate UK

Who is the main contact?
Darran Ball
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Contact information

Type(s)
Public

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Additional identifiers

Integrated Research Application System (IRAS)
283721

Study information

Scientific Title
Lung health checks in Wessex and Yorkshire: integrated biomarker studies

Acronym
iDx Lung

Study objectives
To determine whether adding blood or tissue biomarkers to low-dose CT scanning improves diagnostic performance in risk-stratified population screening for lung cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/04/2021, London - Surrey Research Ethics Committee (Nottingham Centre, The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; +44 (0)207 104 8088, +44 (0)207 104 8102, +44 (0)207 104 8144; surrey.rec@hra.nhs.uk), ref: 21/PR/0211

Primary study design
Observational

Study design
Observational biomarker study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Early detection of lung cancer

Interventions
This is a prospective cohort study for the collection of blood for autoantibody, protein and nucleic acid biomarkers, and nasal epithelium for transcriptomic analysis from individuals attending for lung health checks at mobile scanners in Wessex and Yorkshire. During the period of the study, individuals undergoing a Lung Health Check will be approached by a member of the clinical team or an appropriately trained member of the research team and asked if they are willing to participate in this study. Consent will be taken and samples obtained in mobile units in

convenient community locations, co-located with the clinical evaluation and scanning units of the LHC. No additional clinical data will be collected in the iDx lung biomarker sub-study but biological samples will instead be linked to data collected as part of the main study and all data will be managed by BC platforms. Permissions will also be sought to enable surplus samples to be stored for future research, and for CT scan images to be used for future research.

Intervention Type
Other

Primary outcome(s)
Measured using blood and nasal swab samples for biomarker analysis and clinical data routinely collected for the Lung Health Check (TLHC) at a single visit/timepoint when the patient has their CT scan:
1. Calculation of lung cancer risk stratification efficacy of one or any combination of biomarkers independent from or in combination with existing risk models (LLP/PLCOm2012)
2. Calculation of the alteration in diagnostic accuracy by the addition of one or more biomarkers to low dose CT scanning

Key secondary outcome(s)
Measured using blood and nasal swab samples for biomarker analysis and clinical data routinely collected for the Lung Health Check (TLHC) at a single visit/timepoint when the patient has their CT scan:
1. Cost-efficacy changes from the addition of one or more biomarkers to low dose CT scanning
2. Cost-benefit analysis of proposed optimised clinical algorithm

Completion date
31/01/2027

Eligibility

Key inclusion criteria
1. Individuals undergoing a Lung Health Check
2. Ability to understand the study requirements and provide written informed consent

Participant type(s)
All

Healthy volunteers allowed
No

Age group
All

Sex
All

Key exclusion criteria
1. Deemed medically unfit for sample collection
2. Contraindication for study procedures or sampling

Date of first enrolment
01/03/2021

Date of final enrolment
13/10/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
St. James Hospital
Leeds Teaching Hospitals NHS Trust
Research and Innovation Centre
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Wythenshawe Hospital
Manchester University NHS Foundation Trust
Southmoor Road
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M23 9LT

Study participating centre
Rodney Road Centre
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PO3 6GT

Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Government

Funder Name
Innovate UK

Alternative Name(s)
Technology Strategy Board

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes