

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

Submission date 05/01/2021	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/02/2021	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/10/2024	Condition category Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

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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Study website

<https://www.southampton.ac.uk/ctu/trialportfolio/listoftrials/idx-lung.page>

Contact information

Type(s)

Public

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

283721

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

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

Study design

Observational biomarker study

Primary study design

Observational

Secondary study design

Health economic analysis of biomarkers

Study setting(s)

Other

Study type(s)

Diagnostic

Participant information sheet

These will be made available at https://www.southampton.ac.uk/ctu/trialportfolio/listoftrials/idx-lung.page#essential_trial_documentation (will be uploaded after ethical approval)

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 measure

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

Secondary outcome measures

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

Overall study start date

01/11/2020

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

Age group

All

Sex

Both

Target number of participants

7000

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

England

United Kingdom

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
Wythenshawe
Manchester
United Kingdom
M23 9LT

Study participating centre**Rodney Road Centre**

Illustrious Drive
Portsmouth
United Kingdom
PO3 6GT

Sponsor information

Organisation

University Hospital Southampton NHS Foundation Trust

Sponsor details

SGH, Level E, Laboratory & Pathology Block, SCBR, MP 138
Southampton
England
United Kingdom
SO16 6YD
+44 (0)23 8120 4989
sponsor@uhs.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.uhs.nhs.uk/home.aspx>

ROR

<https://ror.org/0485axj58>

Funder(s)

Funder type

Government

Funder Name

Innovate UK

Alternative Name(s)

innovateuk

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

1. Protocol and other essential documents (PIS, GP letters etc) will be available at https://www.southampton.ac.uk/ctu/trialportfolio/listoftrials/idx-lung.page#essential_trial_documentation
2. The researchers plan to publish in a high-impact peer-reviewed journal by August 2024

Intention to publish date

30/09/2026

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