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Harnessing exhaled breath for lung cancer early detection

Submission date 29/02/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 21/05/2024	**Overall study status** Ongoing	
Last Edited 16/12/2024	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims

Lung cancer causes more deaths than any other cancer due to diagnosis after it has spread. If diagnosed early, before spread, then curative treatment can be offered. Screening programs using CT scans can diagnose lung cancer early and save lives, but they are expensive and can only be applied to people at the very highest risk, which represents less than 40% of people with lung cancer.

Exhalation technology have a device (Inflammacheck) that detects hydrogen peroxide in exhaled breath, which has previously been suggested to be raised in the breath of people who have lung cancer. This is a pilot study that will test whether the inflammacheck device can distinguish lung cancer cases from controls.

Who can participate?

People aged 18 years and over participating in lung health checks or who have been diagnosed with lung cancer but have not started treatment yet.

What does the study involve?

Breathing into two devices (3 minutes each) at a single visit. Briefly, the researchers will recruit 20 people with lung cancer and 20 non-cancer controls who will breathe into the Inflammacheck device where hydrogen peroxide will be measured. They will screen other exhaled compounds to determine if any other biomarkers emerge that are associated with lung cancer and can increase the performance of Inflammacheck.

What are the possible benefits and risks of participating?

There is no direct personal benefit from taking part - this is not a validated test yet so results will not inform treatment decisions. However, participating will help to develop this test so that people in the future may benefit. Risks include minor discomfort from wearing a nose clip and breathing into the device.

Where is the study run from?

Northern Care Alliance Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
June 2023 to December 2026

Who is funding the study?
The Wellcome Trust (UK)

Who is the main contact?
Dr Sean Knight, sean.knight@nca.nhs.uk

Contact information

Type(s)

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
336691

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 60370, IRAS 336691

Study information

Scientific Title
Harnessing exhaled hydrogen peroxide for early lung cancer detection

Acronym
ExPeL

Study objectives
Lung cancer causes an increase in hydrogen peroxide in exhaled breath.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/02/2024, West Midlands Black Country Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)207 104 8010, +44 (0)207 104 8210, +44 (0)207 104 8290; blackcountry.rec@hra.nhs.uk), ref: 24/WM/0028

Study design
Observational; Design type: Case-controlled study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
This is a pilot study assessing whether Inflammacheck can distinguish patients with lung cancer from non-cancer controls. Participants will be identified from outpatient clinics and lung health checks.

This is a case-control study:
Cases: Lung cancer - included if diagnosed with lung cancer, including patients with early-stage (n = 10) and late-stage (n = 10) disease. Patients will be excluded if they have received any lung cancer treatment, have a concurrent alternative active cancer or lack the capacity to consent
Controls: Included if smoking history of more than 20 pack years. Excluded if concurrent active cancer from another organ system or less than 2 years since curative treatment for cancer or lack of capacity to consent (n = 20).

Numbers of participants are the feasibility limit for this study. Participants will be recruited from outpatient clinics and lung health checks. Patients will be approached on the day of their appointment. The research delivery team will describe the study and give a Patient Information Leaflet. After the patient has had time to consider the study and ask any questions, they will provide written consent. This may be on the day of their hospital appointment or at a later date.

If consented on the day of appointment, the participant will be asked to breathe into two Inflammacheck devices. If consented after appointment, a research visit will be planned (at the participant's convenience) where they will be asked to breathe into two Inflammacheck devices

For each participant:
The first Inflammacheck device will return a point-of-care result advising of the level of exhaled hydrogen peroxide The second Inflammacheck device will only collect breath condensate (no point-of-care measurements), which will be stored in a freezer and transferred to researchers at the University of Manchester in batches. They will be analysed by a number of unbiased screening methods including mass spectrometry.
The research delivery team will record the name, hospital number and date of birth linked to a unique study number in a password-controlled file ('Identifier file') stored behind the NHS firewall. They will collect health information including age, gender, smoking history, co-morbidities, pathology and imaging results in a separate file ('Clinical information file'), using the unique study number only as the identifier. The Clinical Information file will be sent to researchers at the University of Manchester (pseudonymised information). At the end of the study the Identifier file will be destroyed thereby fully anonymising the data.

Once participants have provided two Inflammacheck tests, their participation in the study will end.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Exhaled hydrogen peroxide is measured using the Inflammacheck at the time of recruitment

Secondary outcome measures
Exhaled breath condensate collected at recruitment will be analysed by mass spectrometry

Overall study start date
26/06/2023

Completion date
31/12/2026

Eligibility

Key inclusion criteria
Cases:
1. Confirmed diagnosis of lung cancer or highly suggestive radiological findings
2. Aged 18 years or older

Controls:
1. Aged 18 years or over
2. More than 20 pack year history of smoking
3. CT scan negative for lung cancer within the last 2 years

Participant type(s)
Healthy volunteer, Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

Key exclusion criteria
1. Concurrent active non-lung malignancy
2. Curative treatment for a non-lung malignancy less than 2 years previously
3. Treatment for lung cancer
4. Acute infection
5. No capacity to consent

Date of first enrolment
01/04/2024

Date of final enrolment
31/01/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Salford Care Organisation
Stott Lane
Salford
United Kingdom
M6 8HD

Sponsor information

Organisation

Northern Care Alliance NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Research organisation

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

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal within a year of study completion

Intention to publish date
31/12/2027

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary

Published as a supplement to the results publication