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Testing whether home urine kits increase lung cancer screening participation

Submission date
18/07/2025

Recruitment status
Not yet recruiting

Registration date
24/07/2025

Overall study status
Ongoing

Last Edited
16/09/2025

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
Lung cancer is the most common cause of cancer death in the UK, and a high proportion of patients are diagnosed at a late and incurable stage. More than three-quarters of late-stage lung cancer diagnoses in the UK are thought to be preventable, with two of the major risk factors being age and smoking history. The Lung Cancer Screening programme (LCS, formerly called the Targeted Lung Health Check) was rolled out by NHS England in 2019 to improve early cancer diagnosis and survival. It targets people with a smoking history aged 55-74, who are most at risk of developing lung cancer. Individuals are invited to a lung health assessment, and those found to be high risk for cancer are referred for a low-dose CT scan to look for signs of cancer. Over 1.5 million people have been invited to take part in the LCS, but more than 50% of the invites are unanswered, with the major barriers being fear of a cancer diagnosis, fear of radiation exposure during a CT scan, and practical barriers such as travel expense and having to take time off work. One way of overcoming these barriers and increasing participation in LCS might be to offer home-based testing, which may be more convenient and acceptable to invitees. Urine home collection has been shown to be acceptable as a sampling method for men and women in the US and Europe; however, there is very limited data on the uptake in non-responding cancer screening cohorts. UH-CAN LUNG is a feasibility study to understand if people who don't engage with the LCS programme (LCS non-responders) will return a home-collected urine sample analysable for a multi-cancer early detection test. Sampling kits will be sent to 1000 people who have not responded to the LCS invitation, to measure the rate of response with a urine sample and questionnaire.

Who can participate?
1,000 people aged 55-74 with a smoking history, who have failed to respond to LCS invitations from Southampton's LCS service, will be invited to take part by receiving a study kit in the post.

What does the study involve?
Participants will be invited to take part by receiving a study kit in the post. They will be asked to:
1. Read the participant information sheet
2. Read and sign a consent form
3. Answer 5 questions on a questionnaire
4. Provide a small urine sample using the kit and instructions given

5. Returning the consent form, urine sample and questionnaire to the study team using pre-paid shipping.
There will be no contact with participants for follow-up, but the study team will find out the total number of invited participants who go on to book an LCS assessment or are found eligible for a low-dose CT scan of their lungs within 1 month of being sent a study kit. If a consent form is signed and returned, the study team will also find out whether the participant is diagnosed with a suspected lung cancer or not.

What are the possible benefits and risks of participating?
Joining UH-CAN LUNG is an act to help others. Participants will be giving their time and sample for free to help researchers improve LCS options, which could benefit future people by giving more options to take part in screening to diagnose more cancers early. Participating in this study may also act as a reminder to book an appointment for LCS.

There is very little risk in taking part. The device for collecting the urine sample is not invasive. Participants may be falsely reassured that taking part in this study is screening for cancer. It is not, and participants are encouraged to book an appointment for LCS. All efforts will be made to keep participant data protected and identity private, but in the unlikely event that there is a security breach, there is a small risk that someone could see or use the data the study collects about participants.

Where is the study run from?
University Hospital Southampton NHS Foundation Trust is the study Sponsor and is partnering with the Early Diagnosis team at the Southampton Clinical Trials Unit, a team of cancer researchers employed by the University of Southampton who are based at University Hospital Southampton NHS Trust.

When is the study starting and how long is it expected to run for?
The study started in March 2025 and will invite people to take part from September 2025 – December 2025. Data will be collected until March 2026.

Who is funding the study?
The Jon Moulton Charitable Trust.

Who is the main contact?
Hannah Warming, Trial Manager
uhcan@soton.ac.uk

Study website
https://www.southampton.ac.uk/ctu/trialportfolio/listoftrials/uhcan.page#trial_overview

Contact information

Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
356831

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 68754

Study information

Scientific Title
Urine home collection for lung cancer risk assessment in lung cancer screening non-responders

Acronym

UH-CAN LUNG

Study objectives
Improving early diagnosis of cancer is a priority in the NHS Long Term Plan. The Lung Cancer Screening (LCS) programme (previously called the Targeted Lung Health Check) was introduced in 2019; however, fewer than 50% of those invited engage with the programme.

The UH-CAN LUNG study aims to understand if offering home-collected urine sampling as a screening option will increase engagement in the LCS.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/06/2025, South Central - Oxford A Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, United Kingdom; +44 (0)2071048241; oxforda.rec@hra.nhs.uk), ref: 25/SC/0182

Study design
Non-randomized feasibility study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Home

Study type(s)
Screening

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

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

Interventions
UH-CAN LUNG is a non-randomised feasibility study which will help us to understand if LCS non-responders will perform a self-administered urine home collection kit to provide a viable sample for assessment using a novel cancer biomarker being evaluated in other studies.

This is an observational feasibility study in which people who do not engage with the existing NHS Lung Cancer Screening programme (LCS non-responders) will receive a study kit containing information, a consent form, a questionnaire and a urine collection kit with pre-paid postage to return the study materials.

The rate of return of urine samples will be quantified, and the urine will be tested to measure levels of glycosaminoglycans (GAGs), which will inform the viability of home-collected urine samples sent in the post for cancer risk testing. A questionnaire provided with the study kit will inform on reasons for non-engagement with the LCS programme, and opinions on urine testing for lung cancer screening. Together, these data will measure the acceptability and viability of urine sampling at home as a future option for increasing uptake of lung cancer screening.

The study will also collect data on what proportion of study participants book an LCS assessment within 1 month of being posted a study kit, and how many of those are eligible for a low-dose CT scan as a result of being found high risk for a lung cancer diagnosis. The study will also evaluate how many consenting participants receive a suspected lung cancer diagnosis as a result of engaging with the LCS programme.

Intervention Type
Other

Primary outcome measure
The proportion of LCS non-responders will be measured using the number of returned urine samples that are viable for Multi-Cancer Early Detection (MCED) testing

Secondary outcome measures
1. The total number of urine samples will be measured using study data of the number of returned urine samples over 3ml in volume and within 1 month of posting to the participant
2. LCS assessment booking rate by participants measured using study data (within 1 month of being posted a UH-CAN urine home collection kit)
3. Low-dose CT Scan eligibility in LCS non-responders measured using study data (booked within 1 month of being posted a UH-CAN urine home collection kit)
4. Suspected lung cancer diagnoses in participants returning a consent form who engage with the LCS programme (within 1 month of being posted a UH-CAN urine home collection kit), measured using medical notes
5. Participant satisfaction and choices are measured using the UH-CAN LUNG Study Questionnaire within 1 month of being posted a UH-CAN urine home collection kit
6. The return rate of urine samples within 1 month of being posted a UH-CAN urine home collection kit, stratified by the following variables measured using study data at baseline (single time point):
6.1. IMD quintile
6.2. Quintiles for neighbourhood PM2.5, PM10, NO2, NOx, CO, SO2 and ozone exposure.
6.3. Quintiles for time to nearest hospital
6.4. Age bracket
6.5. Gender

Overall study start date
31/03/2025

Completion date
31/03/2026

Eligibility

Key inclusion criteria

1. Invited and twice reminded to participate in the LCS programme.
2. No response received by the LCS team within two weeks of the second reminder to take part (classified as a LCS non-responder).
3. Return of a completed ICF.

Participant type(s)
Patient

Age group
Mixed

Lower age limit
55 Years

Upper age limit
74 Years

Sex
Both

Target number of participants
1000

Key exclusion criteria
1. Previous enrolment in the LCS programme.

Date of first enrolment
15/10/2025

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust

Sponsor details
R&D Department
University Hospital Southampton NHS Foundation Trust
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MP138, Southampton General Hospital
Tremona Road
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Sponsor type
Hospital/treatment centre

Website
https://www.uhs.nhs.uk/

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Charity

Funder Name
Jon Moulton Charity Trust

Alternative Name(s)
The Jon Moulton Charity Trust

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.

Intention to publish date
31/03/2027

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