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Feasibility of home urine collection for lung health check

Submission date
16/07/2026

Recruitment status
No longer recruiting

Registration date
04/08/2026

Overall study status
Ongoing

Last Edited
29/07/2026

Condition category
Cancer

[_] 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
Early detection of lung cancer (e.g., using low-dose CT screening, as in the NHS Targeted Lung Health Check [TLHC]) saves lives. However, this is currently only used for those considered high risk based on questionnaire-based risk scores dominated by age and smoking. Also, the thought of having to have a scan can be off-putting.
An independent measure of cancer risk can be provided by molecules (glycosaminoglycans [GAGs]) found in urine; these can be provided as home-use kits (where people send a urine sample by post) and may also identify high-risk people who have not smoked as much (currently not offered a low-dose CT scan).
This is a feasibility study run by the University of Liverpool to determine if those who are currently invited for the NHS TLHC (aged 55 to 74 years with any history of smoking) will provide home urine samples, whether or not they have responded to their TLHC invite, and (if they responded) whether they are either high- or low-risk by current risk scores.
The data generated by this feasibility study will be used to design larger studies of a suitable size to determine if the GAG biomarkers will aid early cancer detection, improve on current cancer risk scores, and ultimately help save lives.

Who can participate?
People who are currently invited for the NHS TLHC (aged 55 to 74 years with any history of smoking)

What does the study involve?
Invites will be sent by Liverpool University Biobank, who will also receive the urine samples up to February 2026. Those who have not, so far, accepted their TLHC invite will be encouraged to do so, and it is hoped that this novel approach for home sample collection will inspire them to engage. Part of each sample will be sent to a Swedish company (Elypta AB) that is funding the study and will measure the GAG biomarkers.

What are the possible benefits and risks of participating?
Participants who engage with the lung cancer screening program may benefit. Participants will

not get their results (as the tests have not been fully validated yet), and they will not be used to change treatment (participants will continue with their usual care). As an observational study, there is no significant risk to participants.

Where is the study run from?
The University of Liverpool (UK)

When is the study starting and how long is it expected to run for?
August 2025 to October 2026

Who is funding the study?
Elypta AB (Sweden)

Who is the main contact?
Prof. John Field, j.k.field@liverpool.ac.uk

Contact information

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Principal investigator, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
344969

Study information

Scientific Title
Feasibility of home urine collection for lung health check (P4-LHC)

Acronym
P4-LHC

Study objectives
The main objective of P4-LHC is to explore the feasibility of a home-collection urine kit to improve engagement in Targeted Lung Health Checks.

Secondary objectives:
1. To assess if those who failed to respond to the original Lung Health Check invitations re-engage when provided with a urine collection kit; to help design a larger study to assess the utility of GAGome biomarkers to identify high-risk individuals for cancer screening.
2. To assess if any of those who were identified as low-risk for lung cancer as part of the Lung Health Check are instead considered high-risk using the GAGome test; to help decide how best to design a larger study comparing the two different risk assessments.
3. To assess if any of those who were identified as high-risk for lung cancer as part of the Lung Health Check are also considered high-risk using the GAGome test; to help decide how best to design a larger study to determine if the GAGome test might help identify those most at risk, potentially speeding up lung cancer diagnosis for those currently requiring a follow-up low-dose CT scan.
4. To provide data that will allow statisticians to model how the urine GAGome test might be best deployed to have a significant impact on the speed of cancer diagnosis and, hence, improved outcomes.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/11/2024, North West - Greater Manchester East Research Ethics Committee (3rd Floor, Barlow House 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)207 104 8000; gmeast.rec@hra.nhs.uk), ref: 24/NW/0283

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied

Lung cancer

Interventions

NHS staff in the TLHC at Liverpool Heart and Chest Hospital will identify 1000 subjects for the University of Liverpool to approach for the study. The chosen subjects represent three major groups for which important questions remain:
1. TLHC non-responders: 500 randomly selected from those who have not yet responded to the TLHC invite (two letters
and a phone call); with unknown risk (unless they subsequently engage with TLHC, as is hoped).
2. TLHC low-risk responders: 250 randomly selected from those who are low risk for lung cancer according to TLHC risk scores (and therefore not currently invited for an LDCT scan).
3. TLHC high-risk responders: 250 randomly selected from those who are high risk for lung cancer and are offered a TLHC low-dose CT scan.

Liverpool University Biobank will securely receive the personal details (name, address and Liverpool Heart and Chest Hospital [LHCH] subject ID); store them in a secure database; create their own Liverpool University Biobank (LUB) Subject ID; and produce a personalised package for each subject approached consisting of:
1. An introductory leaflet (one page) with invite letter on the back (specific to the subject group)
2. A participant information sheet (two pages)
3. A Colli-Pee urine home collection kit (CE-marked kit including how-to-use instructions, a funnel device and a storage tube with lid)
4. A pre-addressed, pre-paid postage kit (to return the urine sample and the consent form)

Access to information and further help will be available online (via QR codes providing access to Immersive Reader-enabled webpages or translation for those with English as a second language) or provided by telephone.
Having read the provided information, P4-LHC participants will complete the consent form, provide a urine sample with the easy-to-use kit, and return both in the envelope provided.
On receipt of the urine samples, the Liverpool University Biobank (LUB) will update its database to record consent and sample receipt and produce sample ID numbers for each subject.
Two tubes will be stored in the LUB freezers (at -80°C) prior to shipment to Elypta AB labs.
The three remaining tubes will be stored in LUB freezers (at -80°C).

Additional data will be supplied by NHS TLHC staff to LUB (and shared anonymously with study researchers), for the 1000 subjects approached and for the population from which those 1000 subjects have been selected (representing those eligible for TLHC in a specific geographical catchment).

The data would include age, sex, IMD decile, whether they responded to the TLHC, whether they were high or low risk for lung cancer (with % risk score from LLPv2 and PLCOm2012), whether they received a TLHC low-dose CT scan, and whether they were diagnosed with lung cancer by the TLHC.

The urine samples received by Elypta AB (the Swedish company that developed the GAGome test) will be analysed for the glycosaminoglycans that make up the GAGome score. The anonymous data will be jointly analysed by the University and Elypta researchers. In this feasibility study the GAGome scores are not shared with the participants.

Intervention Type

Other

Primary outcome(s)
1. Re-engagement in the NHS Lung Cancer Screening Programme measured using updated recruitment data to Lung Cancer Screening (LCS) at 6 months from initial recruitment invite

Key secondary outcome(s)
1. GAGome biomarker measured using quantitative high-performance liquid chromatography (HPLC) at following end of recruitment

Completion date
01/10/2026

Eligibility

Key inclusion criteria
Prior invitation to the Cheshire and Merseyside NHS Lung Cancer Screening Programme (at the time called Targeted Lung Health Check [TLHC]) as identified by Liverpool Heart and Chest Hospital

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
55 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
231

Key exclusion criteria
1. Not included in the NHS Targeted Lung Health Check recruitment or opted out of NHS data sharing
2. Unable to provide consent

Date of first enrolment
15/08/2025

Date of final enrolment
27/02/2026

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Liverpool Heart and Chest Hospital NHS Foundation Trust
Thomas Drive
Liverpool
England
L14 3PE

Sponsor information

Organisation
University of Liverpool

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type

Funder Name
Elypta AB Sweden

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available