

Liquid biopsy testing in the diagnosis of lung cancer

Submission date 03/05/2023	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/06/2023	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/02/2025	Condition category Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Lung Cancer is the third most common cancer in Wales and the majority of patients are diagnosed at an advanced stage. In the current diagnostic pathway, a patient, who is referred to the Rapid Access Lung Clinic by their GP for suspicion of lung cancer from a CT scan, undergoes a biopsy for the collection of a small sample of tissue that is tested in an NHS laboratory. The results of the tissue biopsy are reviewed by clinicians for planning the patient's treatment. In some cases, it can take up to 8 weeks or even longer for the patient to receive their targeted therapy after their GP referral. There is a critical need to improve and shorten the current diagnostic pathway so that patients at an advanced stage of lung cancer can start their treatment before their cancer grows further.

When cancer cells die, they get broken down and their contents, including small pieces of DNA, are released into the blood. This is called circulating tumour DNA (ctDNA). Researchers have developed a new test that looks for ctDNA in the blood and detects the multiple genetic changes leading to tumour development. Finding DNA with genetic differences aids in diagnosing the type of tumour and helps doctors determine which treatment will be most effective.

The results of the ctDNA testing are available in a timely manner. Moreover, taking a blood sample – “liquid biopsy” – is less invasive than a solid tissue biopsy which for some patients is difficult or impossible. In the QuicDNA study, we propose to introduce ctDNA testing to patients with high clinical cancer suspicion with the aim to improve the current lung cancer diagnostic pathway by shortening the timelines between GP referral and treatment allocation and helping clinicians in planning patients' personalised treatments without delay.

- Can ctDNA be used to deliver genomic results to inform treatment decisions sooner than tissue biopsy-based approaches?
- Can we start appropriate, personalised treatment sooner in patients diagnosed with lung cancer in the ctDNA pathway than the standard pathway?
- Can we improve survival in patients with lung cancer by improving access to personalised therapy at an earlier time?

Who can participate?

Patients will be identified by NHS Respiratory Consultants (RC) at Health Boards (HB), who are

responsible for the patient's care. Patients will be approached about the study by their RC during rapid access lung NHS clinic. We will recruit patients with suspected stage III and IV lung cancer based on computer tomography (CT scan): patients who have planned to receive radical treatment such as surgery, radical radiotherapy or chemoradiotherapy will be excluded.

What does the study involve?

- Whole blood samples will be collected from patients with a high suspicion of lung cancer.
- The blood samples will be sent to a laboratory in Cardiff and Vale University Health Board (Cardiff), where we will detect any cancer cells in the blood.
- The Genomic results from the ctDNA test will be made available to the lung cancer multidisciplinary team meeting (MDT), where cancer diagnosis and treatment decisions are made.
- Patients will be followed up for data about their treatment plan and disease progression, if any.

What are the possible benefits and risks of taking part?

We think that the liquid biopsy test identifies cancer and the most appropriate treatment more effectively than the current tissue biopsy. By taking part in this research you are helping us to build confidence in this test so that it can be used in the NHS and help future patients to access a more effective (personalised) therapy as early as possible.

In QuicDNA we are asking you to take one blood test at the same time as your appointment at the Respiratory Clinic. This means that there should not be any extra risk from participating in this study.

Where is the study run from?

The study will be conducted in the Health Boards in Wales. It is coordinated by the Centre for Trials Research, Cardiff University (UK)

When is the study starting and how long is it expected to run for?

February 2023 to January 2026

Who is funding the study?

1. Health and Care Research Wales (HCRW) (UK)
2. Moondance Cancer Initiative (UK)
3. Illumina (USA)
4. Bayer (Germany)
5. Amgen (USA)

Who is the main contact?

Study team, quicdna@cardiff.ac.uk

Public involvement

Patients have been involved in the study's design from the outset and will participate in the management of the project. In addition, ctDNA testing was presented to the Genomic Partnership Wales Patient Sounding Board 2021 and was widely supported.

Study website

https://www.cardiff.ac.uk/centre-for-trials-research/research/studies-and-trials/view/quicdna/_recache

Contact information

Type(s)

Principal Investigator

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Type(s)

Public

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Contact details

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None available
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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

328841

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

8613 (Cardiff & Vale UHB), SS-24 (Aneurin Bevan UHB)

Study information

Scientific Title

QuicDNA - Integration of Liquid Biopsy into Lung Cancer Diagnostic

Acronym

QuicDNA

Study objectives

1. To evaluate whether ctDNA testing performed at an early stage in the lung cancer diagnostic pathway can shorten time to treatment compared to the SoC diagnostic pathway
2. To evaluate whether ctDNA testing performed at an early stage in the lung cancer diagnostic pathway can increase the proportion of patients with advanced lung cancer who received targeted treatment

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 27/07/2023, East Midlands - Leicester Central Research Ethics Committee (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 2071048227; leicestercentral.rec@hra.nhs.uk), ref: 23/EM/0159

Study design

Multi-centre non-interventional biomarker diagnostic feasibility cohort study followed by an expansion cohort

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied

Patients with suspected stage III (excluding radical treatment) and IV lung cancer based on computer tomography (CT scan) and have tissue biopsy (SOC) diagnostic testing planned

Interventions

Patients will be identified by an NHS Respiratory Consultants (RC) at Health Boards and given a copy of the PIS. If the patient is interested in participating, their details will be passed to the Research Nurse (RN), who will obtain informed consent and perform some screening assessments for confirming their eligibility (e.g. record details of which investigations they have had in relation to cancer diagnosis from their medical records and result of standard of care CT scans). Patients with suspected stage III (not requiring radical treatment) and IV lung cancer, Once their eligibility is confirmed, a blood sample will be collected from patient be and sent to a laboratory in Cardiff and Vale University Health Board, where they will detect any cancer cell in

the blood. The results will be forwarded to the RC. No follow up required. If the blood test shows evidence of lung cancer, RC will be recommended to plan their patient's treatment before the results of the tumour tissue biopsy is available (as per standard of care procedure, a biopsy is planned after the patient's first visit at the Respiratory Clinic and done much later than the liquid biopsy testing). Follow up data will be collected from routinely collected health datasets within NHS for 3 years. Participants will be asked to complete a Quality of Life Questionnaire at screening and follow up and provide 2 additional blood samples (at 3 months post treatment and disease progression), if they consent to this optional samples.

Intervention Type

Mixed

Primary outcome measure

Measured using patient records at the end of the study:

1. Time from participant's first appointment at the Rapid Access Clinic to start of treatment allocation in the two cohorts of comparison (liquid biopsy testing vs. tissue SoC tissue biopsy testing) at an early stage in the lung cancer diagnostic pathway
2. Patients' allocation to treatment in the two cohorts of test (liquid biopsy testing vs. tissue SoC tissue biopsy testing) in the lung cancer diagnostic pathway

Secondary outcome measures

Measured using patient records at the end of the study:

1. Time from sample collection to genomic report in the two cohorts of comparison (liquid biopsy vs. SoC tissue biopsy)
2. Time from suspected diagnosis of lung cancer on CT scan until the first day of treatment
3. Detection of actionable variants by NGS ctDNA panel compared to the SOC tissue diagnostic testing
4. Failure to detect actionable variants by NGS ctDNA panel compared to the SOC tissue diagnostic testing
5. Patients' response to treatment (RT), Progression-free survival (PFS) and Overall Survival (OS) in the two cohorts of comparison
6. Number of prevented repeat tissue biopsies in the ctDNA cohort compared to the SoC tissue cohort

Overall study start date

20/02/2023

Completion date

31/01/2026

Eligibility

Key inclusion criteria

1. Be willing and able to provide written informed consent for the study
2. Age 16 years or over on day of signing informed consent
3. Have radiologically suspected advanced stage III (excluding radical treatment) and stage IV lung cancer from CT scan as evaluated and reported by clinical team and/or a radiologist
4. Consent to have a genetic analysis performed on ctDNA from their blood sample
5. Have a performance status of 0 or 3 on the ECOG Performance Scale

Participant type(s)

Patient

Age group

Adult

Lower age limit

16 Years

Sex

Both

Target number of participants

1,260

Key exclusion criteria

1. Is unable or unwilling to comply with study procedures
2. Stage I, II, or III suspected lung cancer that qualifies for radical treatment (surgery, radical radiotherapy or chemoradiotherapy)
3. Have any known concurrent malignancy

Date of first enrolment

01/07/2023

Date of final enrolment

30/06/2025

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre

Aneurin Bevan University Health Board

Ysbyty Ystrad Fawr

Ystrad Fawr Way,

Ystrad Mynach, Hengoed

Caerphilly

United Kingdom

CF82 7GP

Study participating centre

Cardiff and Vale NHS Trust

Cardigan House

University Hospital of Wales

Heath Park

Cardiff
United Kingdom
CF14 4XW

Study participating centre

Hywel Dda NHS Trust

Hafan Derwen
Jobs Well Road
Carmarthen
United Kingdom
SA31 3BB

Study participating centre

Swansea Bay University Local Health Board

Tonna Hospital
Tonna Uchaf
Tonna
Neath
United Kingdom
SA11 3LX

Study participating centre

Betsi Cadwaladr University Lhb Mold Office

Preswylfa
Hendy Road
Mold
United Kingdom
CH7 1PZ

Study participating centre

Cwm Taf Morgannwg University Local Health Board

Dewi Sant Hospital
Albert Road
Pontypridd
United Kingdom
CF37 1LB

Sponsor information

Organisation

Aneurin Bevan University Health Board

Sponsor details

Ystrad Fawr Way Ystrad Mynach Hengoed
Newport
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United Kingdom
CF82 7GP
+44 1495 745656
ABB.RandD@wales.nhs.uk

Sponsor type

Government

Website

<https://abuhb.nhs.wales/>

ROR

<https://ror.org/045gxp391>

Funder(s)

Funder type

Government

Funder Name

Health and Care Research Wales

Alternative Name(s)

Health & Care Research Wales, Ymchwil Iechyd a Gofal Cymru, Health Care Research Wales, HCRW

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

United Kingdom

Funder Name

Amgen

Alternative Name(s)

Amgen Inc., Applied Molecular Genetics Inc.

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Funder Name

Moondance

Funder Name

Eli Lilly and Company

Alternative Name(s)

Lilly, Eli Lilly & Company, Eli Lilly & Co., Eli Lilly And Co

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Funder Name

Illumina

Alternative Name(s)

Illumina, Inc.

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Funder Name

AstraZeneca

Alternative Name(s)

AstraZeneca PLC, Pearl Therapeutics

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United Kingdom

Funder Name

Bayer

Alternative Name(s)

Bayer AG, Bayer Corporation, Friedr. Bayer et. comp.

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

Germany

Results and Publications

Publication and dissemination plan

The results of this project will be sent to participants with a 'thank you' letter. The wider public will be informed via public and social media, Wales Cancer Research Centre, Welsh Cancer BioBank and Genomic Partnership Wales websites. We plan to present results at conferences and through publications in scientific journals. The results will inform the planning of future national cancer pathway and funding for future liquid biopsy services in NHS Wales.

Intention to publish date

15/12/2025

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date