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Liquid biopsy testing in the diagnosis of lung cancer

Submission date
03/05/2023

Recruitment status
No longer recruiting

Registration date
19/06/2023

Overall study status
Ongoing

Last Edited
03/02/2025

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 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.

Contact information

Type(s)
Principal investigator

Contact name
Dr Magda Meissner

ORCID ID
https://orcid.org/0000-0001-5897-0219

Contact details
Velindre Cancer Centre
Whitchurch
Cardiff
United Kingdom
CF14 2TL
+44 29 20615888
meissnerm1@cardiff.ac.uk

Type(s)
Public

Contact name
Mrs Georgina Gardner

Contact details
Neuadd Meirionnydd
Room Floor 6, University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4YS
None available
quicdna@cardiff.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
328841

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Diagnostic

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(s)

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
All

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

ROR
https://ror.org/045gxp391

Funder(s)

Funder type
Government

Funder Name

Health and Care Research Wales

Alternative Name(s)
Health & Care Research Wales, Health Care Research Wales, Ymchwil lechyd a Gofal Cymru, HCRW

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

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, Eli Lilly & 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, AZ

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes