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NHS Cancer Vaccine Launch Pad (NHS CVLP)

Submission date 09/07/2024	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 09/10/2024	**Overall study status** Ongoing	[ ] Statistical analysis plan [ ] Results
Last Edited 09/10/2024	**Condition category** Cancer	[ ] Individual participant data [X] Record updated in last year

Plain English Summary

Background and study aims
Personalised cancer vaccines are a type of cancer treatment designed to target an individual's unique cancer cells. They are created by analysing a patient's tumour and identifying specific DNA changes that are unique to that cancer, then using that information to create a vaccine tailored to that patient. The intention is that the cancer vaccine will stimulate the immune system to specifically recognise and destroy the cancer cells.
The NHS Cancer Vaccine Launch Pad (CVLP) is looking to find people who may be able to take part in research trials for personalised vaccines to treat cancer. By supporting these trials, the CVLP aims to speed up the development of personalised treatments for cancer patients.

Who can participate?
NHS cancer patients in England aged over 16 years with capacity to consent.

What does the study involve?
Upon consent, the following will occur:
1. Small sections of the tumor will be cut from the diagnostic block by a histopathologist (a doctor who specializes in studying tissues). These sections will be sent to CVLP partners for nucleic acid extraction and sequencing. Nucleic acids are molecules like DNA and RNA that carry genetic information.
2. A blood sample, up to 30 milliliters, will be drawn and sent to CVLP partners. This sample may be tested for germline nucleic acid (genetic information you were born with) and tumor circulating free DNA (genetic material released by the tumor into the bloodstream).
3. Baseline demographic (like age and gender) and clinical data will be recorded by the clinical or research team and sent with the biological material in a pseudonymised form (using codes instead of names to protect your identity). This data will also be centrally held by Southampton Clinical Trials Unit (SCTU) to coordinate with cancer vaccine trial partners and sites. A clinical liaison team will oversee this process.
4. During Phase 1, sequencing data will be held by industry partners. If you are eligible for a cancer vaccine trial, the clinical liaison team will inform your clinical team and local trial sites. Pseudonymised codes will be used to identify patients when communicating with clinical teams or linking patients with NHS cancer vaccine trial sites. Any other information shared outside the NHS CVLP framework will also be pseudonymised.

5. If you are eligible for a cancer vaccine trial, your home clinical or research team, or the team at the nearest cancer vaccine trial site, will approach you for further discussion and a separate consent.

What are the possible benefits and risks of participating?
By taking part in the CVLP, participants might be able to take part in a research trial and receive personalised cancer vaccine treatment before it is widely available. For participants who receive this personalised treatment, it may reduce the chance of their cancer growing or coming back. Not everyone will be suitable to take part in a research trial and the research trial may not benefit all participants directly. This is because we are still finding out how effective the treatment might be.
Participants can also benefit from the knowledge that they are helping medical research to improve cancer treatment. The tests and treatments being used were developed with the help of participants who took part in research years ago. The more participants that take part in research, the faster progress can be made as more human samples can be studied.
Where is the study run from?
The study is coordinated by the Southampton Clinical Trials Unit and is being run in NHS hospitals in England. The study is sponsored by NHS England.

When is the study starting and how long is it expected to run for?
May 2023 to December 2030

Who is funding the study?
NHS England (UK)

Who is the main contact?
Southampton Clinical Trials Unit at cvlp@soton.ac.uk

Study website
https://www.southampton.ac.uk/ctu/cancer-vaccine-launch-pad.page#home

Contact information

Type(s)
Scientific

Contact name
Miss Nicole Keyworth

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number
325291

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 57835, IRAS 325291

Study information

Scientific Title
Establishing a UK platform to collect tumour samples and perform DNA/RNA sequencing for the development of personalised cancer vaccines

Acronym
CVLP

Study hypothesis
The objectives of the NHS Cancer Vaccine Launch Pad (CVLP) are to:
1. Identify cancer patients undergoing resection or biopsy of their tumours who could be eligible for personalised mRNA therapies such as cancer vaccines.
2. Create a pathway for collection and transfer of tumour samples, blood samples and pseudonymised clinical data during routine NHS care.
3. Send samples for DNA extraction, molecular analysis and sequencing initially in partnership with industry (Phase 1) and later to be performed by the NHS Genomic Medicine Service (Phase 2).
4. Use the results to accelerate access of eligible cancer patients to cancer vaccine trials.

The programme aims to profile up to 10,000 tumour samples in a phased approach over 7 years. To achieve this we will enrol patients diagnosed with different cancers and seek their consent for:
1. Collection of surplus tumour biopsies or surgical resection samples to be sent to genetic testing laboratories for DNA or RNA extraction and sequencing.
2. Collection of a blood sample to perform relevant tests for cancer vaccines, eg: circulating free tumour DNA or sequencing of healthy cells to compare to the tumour.
3. Collection of routine clinical data on demographics, staging, diagnostic tests, treatment and outcomes.
4. The linkage of this data in a database held by a central team to co-ordinate between clinical sites, industry partners and cancer vaccine trial sites.
5. Onwards referral of potentially eligible patients to CV trials or linked research studies provided relevant research ethics approval has been granted - for which separate consent will be sought.

No specific therapeutic intervention will be carried out under this protocol and any activities for the CVLP will happen in addition to routine genetic testing that is carried out as standard of care. If CV gain regulatory approval we hope the CVLP pathway will become part of routine care.

Ethics approval required

Ethics approval required

Ethics approval(s)
Approved 20/08/2023, East of England – Essex Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8177; essex.rec@hra.nhs.uk), ref: 23/EE/0178

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital, Medical and other records

Study type(s)
Other

Participant information sheet
See outputs table

Condition
Cancer vaccine studies in various cancer types

Interventions
Eligible patients with a number of different cancers will be approached around the time of diagnostic biopsy or surgical resection. This could be either during their initial diagnosis of cancer or at the time of recurrence. In all cases the patient will be aware that a diagnosis of cancer has already been made, or is a strong possibility. The patient will be approached by the clinical team managing their care to discuss the study and a standard patient information sheet will be provided.

Patients who agree to take part will have their informed consent confirmed and recorded by one of the clinical team or a research associate.

Following consent, the following will occur:
1. Cuttings of sections of tumour from the diagnostic block under the supervision of a histopathologist, for forwarding to CVLP partners (Phase 1) for extraction and sequencing of nucleic acid.
2. Drawing of a blood sample (up to 30mls) also for forwarding to CVLP partners. Potential tests performed on blood samples include germline extraction of nucleic acid for the comparison with the tumour sample or tumour circulating free tumour DNA.
3. Recording of baseline demographic and clinical data will be done by the clinical or research team. This will be sent along with biological material in a pseudonymised form. Data will be held centrally by the Southampton Clinical Trials Unit (SCTU).
4. During Phase 1 sequencing data will be held by industry partners. If a patient is deemed to be eligible for a cancer vaccine trial this will be fed back to the clinical liaison team who will inform

the clinical teams and any local trial sites. The pseudonymised codes will only be used for re-identifying patients when communicating with the clinical team or to link patients with NHS cancer vaccine trial sites. Any other information shared outside the NHS CVLP framework will be pseudonymised.
5. If a patient is deemed eligible for a cancer vaccine trial they will be approached by either their home clinical or research team, or by the team at the nearest cancer vaccine trial site for further discussion and a separate consent.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Number of participants recruited to the CVLP by September 2024
2. Number of participants recruited to the CVLP measured every 12 months until study closure
3. Proportion of eligible patients approached that consent to participate in the CVLP measured every 12 months until study closure
4. Proportion of tumour samples available for analysis measured at 2 weeks post consent to a cancer vaccine trial
5. Number of participants proceeding to participate in a cancer vaccine trial measured monthly until study closure

Secondary outcome measures
Number of sequencing outputs from NHS laboratories used for manufacturing of therapeutic personalised cancer vaccines measured every 12 months until study closure

Overall study start date
01/05/2023

Overall study end date
31/12/2030

Eligibility

Participant inclusion criteria
1. Be over the age of 16 years
2. Have a tumour which has been, or will be resected or biopsied
3. Have the capacity to consent to involvement in the CVLP
4. Have sufficient tumour available for genomic analyses

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
10,000

Participant exclusion criteria
1. Under the age of 16 years
2. Incapable of giving informed consent

Recruitment start date
31/08/2024

Recruitment end date
01/05/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Maidstone
Maidstone Hospital
Hermitage Lane
Maidstone
United Kingdom
ME16 9QQ

Study participating centre
Tunbridge Wells Hospital
The Tunbridge Wells Hospital
Tonbridge Road
Pembury
Tunbridge Wells
United Kingdom
TN2 4QJ

Study participating centre
Southampton
Southampton General Hospital
Tremona Road
Southampton

United Kingdom
SO16 6YD

Study participating centre
University Hospital Lewisham
Lewisham High Street
London
United Kingdom
SE13 6LH

Study participating centre
Queen Elizabeth Hospital
Woolwich Stadium Road
Woolwich
London
United Kingdom
SE18 4QH

Study participating centre
Royal Surrey County Hospital
Egerton Road
Guildford
United Kingdom
GU2 7XX

Study participating centre
Royal Sussex County Hospital
Eastern Road
Brighton
United Kingdom
BN2 5BE

Study participating centre
Conquest Hospital
The Ridge
St. Leonards-on-sea
United Kingdom
TN37 7RD

Study participating centre
Eastbourne District General Hospital
Kings Drive
Eastbourne
United Kingdom
BN21 2UD

Study participating centre
Addenbrookes
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Queens Hospital
Rom Valley Way
Romford
United Kingdom
RM7 0AG

Study participating centre
Colchester General Hospital
Colchester District General Hosp.
Charter Way
Turner Road
Colchester
United Kingdom
CO4 5JL

Study participating centre
Ipswich Hospital
Heath Road
Ipswich
United Kingdom
IP4 5PD

Study participating centre
Stoke Mandeville Hospital
Mandeville Road

Aylesbury
United Kingdom
HP21 8AL

Study participating centre
Wycombe Hospital
Queen Alexandra Road
High Wycombe
United Kingdom
HP11 2TT

Study participating centre
Hillingdon Hospital
Hillingdon Hospital
Pield Heath Road
Uxbridge
United Kingdom
UB8 3NN

Study participating centre
Churchill Hospital
Churchill Hospital
Old Road
Headington
Oxford
United Kingdom
OX3 7LE

Study participating centre
Queens Medical Centre, Nottingham University Hospital
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Nottingham City Hospital
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Study participating centre
Warwick Hospital
Lakin Road
Warwick
United Kingdom
CV34 5BW

Study participating centre
New Cross Hospital Royal Wolverhampton
Wolverhampton Road
Heath Town
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Walsall Manor Hospital
Moat Road
Walsall
United Kingdom
WS2 9PS

Study participating centre
Royal Stoke University Hospital
Newcastle Road
Stoke-on-trent
United Kingdom
ST4 6QG

Study participating centre
Salford Royal Hospital
Stott Lane
Eccles
Salford
United Kingdom
M6 8HD

Study participating centre

The Royal Oldham Hospital
Rochdale Road
Oldham
United Kingdom
OL1 2JH

Study participating centre
Fairfield General Hospital
Fairfield General Hospital
Rochdale Old Road
Bury
United Kingdom
BL9 7TD

Study participating centre
Rochdale Infirmary
Whitehall Street
Rochdale
United Kingdom
OL12 0NB

Study participating centre
St. James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX

Study participating centre
Weston Park Hospital
Whitham Road
Sheffield
United Kingdom
S10 2SJ

Study participating centre
Derriford Hospital
Derriford Road
Derriford
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Musgrove Park Hospital
Parkfield Drive
Taunton
United Kingdom
TA1 5DA

Study participating centre
Yeovil District Hospital
Higher Kingston
Yeovil
United Kingdom
BA21 4AT

Study participating centre
Royal Devon and Exeter Hospital
Royal Devon & Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
North Devon District Hospital
Raleigh Park
Barnstaple
United Kingdom
EX31 4JB

Study participating centre

Bristol Haematology & Oncology Centre
Horfield Road
Bristol
United Kingdom
BS2 8ED

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Royal United Hospital Bath
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
Cheltenham General Hospital
Sandford Road
Cheltenham
United Kingdom
GL53 7AN

Study participating centre
Gloucestershire Royal Hospital
Great Western Road
Gloucester
United Kingdom
GL1 3NN

Study participating centre
Royal Lancaster Infirmary
Ashton Road
Lancaster
United Kingdom
LA1 4RP

Study participating centre
Royal Blackburn Hospital
Haslingden Road
Blackburn
United Kingdom
BB2 3HH

Study participating centre
Cumberland Infirmary
Newtown Road
Carlisle
United Kingdom
CA2 7HY

Study participating centre
West Cumberland Hospital
Homewood
Hensingham
Whitehaven
United Kingdom
CA28 8JG

Study participating centre
Sunderland Royal Hospital
Kayll Road
Sunderland
United Kingdom
SR4 7TP

Study participating centre
South Tyneside District General Hospital
Harton Lane
South Shields
United Kingdom
NE34 0PL

Study participating centre

The James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
North Tyneside General Hospital
Rake Lane
North Shields
United Kingdom
NE29 8NH

Sponsor information

Organisation
NHS England

Sponsor details
Wellington House, 133-155 Waterloo Road
London
England
United Kingdom
SE1 8UG
-
england.cancervaccinelaunchpad@nhs.net

Sponsor type
Government

Funder(s)

Funder type
Industry

Funder Name
NHS England as sponsor will be receiving funding from multiple industry companies

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/12/2031

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?
Participant information sheet	version 8	22/03/2024	23/07/2024	No	Yes