NHS Cancer Vaccine Launch Pad (NHS CVLP)

Submission date 09/07/2024	Recruitment status Recruiting	Prospectively registeredProtocol		
Registration date	Overall study status Ongoing Condition category	Statistical analysis plan		
09/10/2024		☐ Results		
Last Edited		Individual participant data		
23/05/2025	Cancer	[X] Record updated in last year		

Plain English summary of protocol

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

Contact information

Type(s)

Scientific

Contact name

Miss Nicole Keyworth

Contact details

Southampton Clinical Trials Unit, Southampton General Hospital Southampton United Kingdom SO16 6YD +44 2381205154 cvlp@soton.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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 objectives

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

Study type(s)

Other

Health condition(s) or problem(s) studied

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 reidentifying 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

Primary outcome(s)

- 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

Key secondary outcome(s))

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

Completion date

31/12/2030

Eligibility

Key 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

16 years

Sex

Αll

Key exclusion criteria

- 1. Under the age of 16 years
- 2. Incapable of giving informed consent

Date of first enrolment

31/08/2024

Date of final enrolment

Locations

Countries of recruitment

United Kingdom

England

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

Study participating centre Broomfield University Hospital

Broomfield Hospital Court Road Chelmsford United Kingdom CM1 7ET

Study participating centre Basildon University Hospital

Nethermayne Basildon United Kingdom SS16 5NL

Study participating centre Southend University Hospital

Prittlewell Chase Westcliff-on-sea United Kingdom SSO ORY

Study participating centre Royal Bournemouth General Hospital

Castle Lane East Bournemouth United Kingdom BH7 7DW

Study participating centre Poole Hospital

Longfleet Road Poole United Kingdom BH15 2JB

Study participating centre

St Marks Hospital

Watford Road Harrow United Kingdom HA1 3UJ

Study participating centre East Surrey Hospital

Canada Avenue Redhill United Kingdom RH1 5RH

Study participating centre Basingstoke and North Hampshire Hospital

Aldermaston Road Basingstoke United Kingdom RG24 9NA

Study participating centre University Hospital of North Tees

Hardwick Road Stockton-on-tees United Kingdom TS19 8PE

Study participating centre Great Western Hospital

Marlborough Road Swindon United Kingdom SN3 6BB

Study participating centre Milton Keynes University Hospital

Standing Way
Eaglestone
Milton Keynes
United Kingdom
MK6 5LD

Study participating centre Royal Hampshire County Hospital

Romsey Road Winchester United Kingdom SO22 5DG

Study participating centre Castle Hill Hospital

Castle Road Cottingham United Kingdom HU16 5JX

Study participating centre Bedford Hospital South

Kempston Road Bedford United Kingdom MK42 9DJ

Study participating centre Luton and Dunstable University Hospital

Lewsey Road Luton United Kingdom LU4 0DZ

Study participating centre West Middlesex University Hospital

Twickenham Road Isleworth United Kingdom TW7 6AF

Study participating centre
University Hospital Coventry & Warwickshire
Clifford Bridge Road

Walsgrave Coventry United Kingdom CV2 2DX

Study participating centre Russells Hall Hospital

Pensnett Road Dudley United Kingdom DY1 2HQ

Study participating centre Manchester Royal Royal Infirmary

Cobbett House Oxford Road Manchester United Kingdom M13 9WL

Study participating centre Wythenshawe Hospital

Southmoor Road Wythenshawe Manchester United Kingdom M23 9LT

Study participating centre Chesterfield Royal Hospital

Chesterfield Road Calow Chesterfield United Kingdom S44 5BL

Study participating centre Harrogate District Hospital

Lancaster Park Road

Harrogate United Kingdom HG2 7SX

Study participating centre Rotherham General Hospital

Moorgate Road Rotherham United Kingdom S60 2UD

Sponsor information

Organisation

NHS England

Funder(s)

Funder type

Industry

Funder Name

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

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?
Participant information sheet	version 8	22/03/2024	23/07/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes