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A clinical trial testing vaccines designed to prevent lung cancer in people at risk of recurrent or new lung cancer

Submission date
17/03/2026

Recruitment status
Recruiting

Registration date
26/05/2026

Overall study status
Ongoing

Last Edited
18/06/2026

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 most common cause of cancer death that society faces. It kills almost 35,000 people every year in the UK.
Although it is one of the most lethal cancers, it is also one of the most preventable because it takes a long time for lung cancer to develop and there are clear risk factors. We now know that the earliest changes in persistent smokers are subtle changes to the cells lining their lungs and airways. The first are mutations to genes contained within these cells. Cells which contain mutated genes send out distress signals like flags displayed by a ship in danger. These short protein flags are called neoantigens. The immune system recognises most cells bearing these neoantigen “flags” and kills them. However, the immune system sometimes does not recognise or kill these ‘flag-waving’ cells. As a result, cells can survive, develop more mutations, and grow to become lung cancer over years or even decades. Eventually, these tumours cause symptoms like a cough or shortness of breath and can be seen on an X-ray or CT scan. The vaccine (ChAdOx2 LungVax) “teaches” the immune system to recognise and kill every cell that carries these neoantigens, preventing them from developing into lung cancer.

Who can participate?
The trial will assess the safety and effectiveness of ChAdOx2 LungVax in two distinct sets of high cancer risk individuals. The first set are individuals who have recently had curative surgery for early-stage non-small cell lung cancer (NSCLC). The second set are individuals who are participating in the NHS Lung Cancer Screening Programme - who are at elevated risk of NSCLC and other cancers, but have not had a cancer diagnosis.

What does the study involve?
Participants will be vaccinated with ChAdOx2 LungVax four times over an 18-month period.

What are the possible benefits and risks of participating?
Benefits:
Not provided at time of registration
Risk: ChAdOx2 LungVax has not been given to human subjects before

Minimisation of risk: ChAdOx2 LungVax, is a replication-deficient simian adenovirus ChAdOx2 vector expressing 22 LungVax hotspot mutations and the NYESO-1 and MUC1 cancer antigens. The ChAdOx2 vector is derived from simian adenovirus ChAd68. The ChAdOx2 vector is replication-deficient as the E1 gene region, essential for viral replication, has been deleted. Because of the E1 deletion, the virus can only propagate in cells expressing E1 functions, and thus virus is unable to replicate within vaccinated animals or humans. To ensure overall participant safety: the first participant in Cohort 1 will be enrolled at least 48 hours before subsequent participants, enabling Day0 - Day2 adverse events to be assessed before dosing of the next participant. Provided there are no safety concerns, as assessed by the Trial Management Group (TMG) a further two participants will be vaccinated at least 1 hour apart. The trial TMG will perform a comprehensive safety evaluation of Cohort 1, 28 days after the last participant has received their initial vaccination. If less than 4 Dose Limiting Toxicities are observed in Cohort 1, we will then commence enrolment into Cohort 2.
Risk: Administering LungVax
Minimisation of risk: Assessment of Haemoglobin, white cell count with differential count (neutrophils and lymphocytes) and platelets will be completed prior to administration of ChAdOx2 LungVax. No potential drug reactions are known for ChAdOx2 LungVax. ChAdOx2 LungVax is unlikely to interfere directly with the cytochrome P450-mediated metabolism of other drugs. There are no human or animal data regarding overdose of ChAdOx2 LungVax and no non-clinical single or repeat dose toxicology studies have been performed. Should an overdose occur, participants should be carefully monitored, and management should be supportive and tailored to symptoms as they arise. Any participant who inadvertently receives a higher dose than intended should be monitored closely, managed with appropriate supportive care until recovery and followed up expectantly. Management of overdose should include monitoring for toxicity, general supportive measures including monitoring of symptoms and haematological parameters, and treatment provided based on any signs or symptoms experienced.
Risk: There is a risk associated with additional research blood sample collection; blood samples could cause pain, bruising or bleeding.
Risk minimisation: The trial will be conducted at a hospital with expertise in the treatment and diagnosis of NSCLC to ensure the highest standard of care for participants. The trial has undergone a risk assessment involving the operational team, oncology consultants, nursing team, and statistician. The trial set-up has also involved patient involvement, with 3 members from a PPI group who have lived experience of cancer. Meetings have been held to review the participant pathway through the trial, and also discuss the sampling schedule and visit burden, in addition to patient-facing documentation, their input has tailored how the trial is presented to potential participants . These PPI members will also sit on the Trial Management Group and Trial Steering Committee.
Burden: Attending trial visits at the investigator site . This may be a particular burden to participants in Cohort 2 - as they are not under post-surgical surveillance, they may need to visit the hospital solely for trial visits.
Burden minimisation: Investigator sites will be informed to align trial visits to when participants are already visiting the hospital (where possible) and to inform participants of the dates of upcoming trial visits as early as possible, to allow maximum notice. The burden of attending trial visits is clearly explained in the participant information sheet and will be explained during the screening trial visit, allowing potential participants can understand what is involved if they consent to take part. If the investigator site can facilitate, participants will be informed that a family/friend can attend trial visits with them for support. Reasonable travel expenses will also be reimbursed as per local policy.

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

When is the study starting and how long is it expected to run for?
June 2026 to December 2030

Who is funding the study?
Cancer Research UK
CRIS Cancer Foundation

Who is the main contact?
octo-lungvax@oncology.ox.ac.uk

Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

Integrated Research Application System (IRAS)
1013101

Central Portfolio Management System (CPMS)
55929

Sponsor's protocol code number
OCTRU428

Study information

Scientific Title
A Modular Cohort-Based Precision-Prevention Trial of neoantigen-targeting vaccines to prevent cancer in individuals at risk of recurrent or new non-small cell lung cancer (NSCLC) and other cancers

Acronym
LungVax

Study objectives
Primary objective:
To determine the safety and immunogenicity (magnitude) of ChAdOx2 LungVax

Secondary objectives:
1. Assessment of longer-term safety and tolerability of ChAdOx2 LungVax
2. To determine the immunogenicity (breadth) of ChAdOx2 LungVax
3. Assessment of longer-term immunogenicity of ChAdOx2 LungVax

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/05/2026, Wales Research Ethics Committee 1 Cardiff (Health and Care Research Wales Castlebridge 4 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; -; Wales. REC1@wales.nhs.uk), ref: 26/WA/0090

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking

Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Safety

Study type(s)

Health condition(s) or problem(s) studied
Surgically resected stage 1A/1B non small cell lung cancer

Interventions
This phase of the LungVax trial includes two cohorts. Both cohorts will receive the intervention, ChAdOx2 LungVax, via intramuscular injection at a dose of 5 x 10^10 vp on day (D)0 and D28, month (M)12 and M18. Both cohorts will be followed up for 2 years post first vaccination to record longer term toxicity and immunogenicity
Cohort 1 will recruit 20 patients who have undergone successful (R0/R1) surgical resection for Stage 1A/1B NSCLC within 3 months of surgery. These participants will be followed up for 2 years post first vaccination to record longer term toxicity and immunogenicity during which time they will undergo 6-monthly CT chest, abdomen and pelvis imaging to exclude new or recurrent cancers.
Cohort 2 will involve 20 individuals drawn from the NHS Lung Cancer Screening Programme, who have been identified as being at elevated risk of NSCLC and other cancers. These participants would have undergone a low-dose CT assessment or other imaging, within 3 months prior to enrolment, that has excluded the presence of cancer. These participants will also undergo a low-dose CT scan at approximately 24 months after the baseline (screening) scan, in line with routine imaging and current standard of care within the NHS Cancer screening Programme.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
ChAdOx2 LungVax

Primary outcome(s)
1. Number and severity of adverse events (AEs) within the DLT evaluable period (28 days after first vaccination at D0) within each cohort. Measured using vaccine-emergent AEs or clinically significant laboratory changes (per CTCAE v6.0) or changes in vital signs within each cohort
2. Magnitude of vaccine antigen specific cellular immunogenicity using peripheral-blood mononuclear cells (PBMCs) (e.g. for Interferon gamma (IFNγ) enzyme-linked immunospot (ELISpot) assay). Measured at Day 0 and Day 14

Key secondary outcome(s)

1. Total number and severity of AESIs and SAEs in each cohort (within and outside the DLT evaluable period), comprising treatment - emergent AESIs and SAEs. Measured at 24 months after vaccination at Day 0 or Early Withdrawal Visit (EWV)
2. Breadth of vaccine antigen specific immune responses defined as the number of peptides /peptide pools targeted by vaccine specific T cells at peak response (spot-forming units (SFUs) /million PBMCs) relative to negative control in each assay. Measured at Day 0 and Day 14
3. Cellular immunogenicity (as above for primary end point). Measured during the 24-month follow-up and at 24 months after vaccination at Day 0
4. Responses to vaccine antigens restricted by Human leukocyte antigens (HLA) alleles, e.g. using ELISpot (and/or intracellular cytokine assays) against selected peptide antigens. Measured during the 24-month follow-up and at 24 months after vaccination at Day 0

Completion date
31/12/2030

Eligibility

Key inclusion criteria
Cohort 1:
1. Age ≥18 years.
2. Histological confirmation of NSCLC.
3. Curative surgery in keeping with NICE guidelines for stage IA or IB NSCLC ≤ 3 months of D0.
4. Post-operative imaging confirming no active cancer (within 3 months/≤90 (+/- 7) days of Day 0).
5. Laboratory parameters (tested during screening period and results obtained prior to vaccine administration) within the ranges specified in the protocol.
6. For participants of childbearing potential only (as defined by protocol section 5.1): willing to use effective contraception for the duration of the study and a negative pregnancy test on the days of screening and vaccination.
7. Willing and able to comply with the protocol scheduled visits and investigations for the duration of the trial.

Cohort 2:
1. Age 55–74 years inclusive, in accordance with NHS Lung Cancer Screening Programme eligibility.
2. Participating in NHS Lung Cancer Screening Programme with recent (within 3 months/≤90 (+/- 7) days of Day 0) low dose CT scan/or other imaging confirming no active cancer or suspicion of cancer.
3. Haemoglobin (Hb), white cell count (WCC) and platelets (tested during screening period, prior to vaccine administration) within the normal ranges specified (local lab ranges).
4. For participants of childbearing potential only (as defined by protocol section 5.1): willing to use effective contraception for the duration of the study and a negative pregnancy test on the days of screening and vaccination.
5. Willing and able to comply with the protocol scheduled visits and investigations for the duration of the trial.

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
74 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Cohort 1:
1. Positive surgical margins or incomplete resection (R2 macroscopic resection on post-operative pathological assessment).
2. Other/active malignancy or cancer requiring systemic treatment within the past 2 years apart from non-melanomatous skin cancer, stage 0 melanoma in situ, breast ductal carcinoma in situ (DCIS), polyps and in situ cervical cancer. Or, other new or recurrent cancer diagnosed previously that is currently being treated or maintained in remission (including by hormonal therapy).
3. Prior, or eligible for, neoadjuvant or adjuvant treatment.
4. Currently pregnant or breast-feeding.
5. Prior history of thromboembolic events such as myocardial infarction, angina, cerebrovascular accident/TIA/stroke, pulmonary embolus or deep vein thrombosis.
6. History of heparin-induced thrombocytopenia and thrombosis (HITT or HIT type 2).
7. Active autoimmune disease. e.g. Crohn's disease, rheumatoid arthritis.
8. Confirmed active diagnosis of known high-risk infections (e.g., Human Immunodeficiency Virus) (HIV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) or syphilis infection, tuberculosis and Creutzfeldt-Jacob disease) unless participant case is of a particular scientific interest and agreed in advance with CI or delegate.
9. Any significant or uncontrolled disease or condition that, in the clinical judgment of the treating physician, is likely to interfere with evaluation of trial treatment, interpretation of participant safety or trial results, prevent the participant from complying with any aspect of the protocol or that may put the participant at unacceptable risk.
10. Live or live-attenuated vaccine administered less than 14 days before the first ChAdOx2 LungVax vaccination (Day 0).
11. Any disorder that is clinically relevant to the participants current health or vaccine response, as judged by the investigator, including known primary or secondary immunodeficiencies, ongoing immunosuppressive therapy, or laboratory evidence of immune compromise.
12. Severe hypersensitivity (≥Grade 3) to ChAdOx1-containing vaccines and/or any of their excipients.
13. Prior administration of ChAdOx2 vaccine.
14. Severe allergy to eggs or any previous vaccination.
15. Current participation in another interventional clinical trial involving the administration of an investigational medicinal product.

Cohort 2:
1. Active malignancy or cancer requiring systemic treatment within the past 2 years apart from non-melanomatous skin cancer, stage 0 melanoma in situ, breast ductal carcinoma in situ (DCIS), polyps and in situ cervical cancer. Or, other new or recurrent cancer diagnosed previously that is currently being treated or maintained in remission (including by hormonal therapy).

2. Currently pregnant or breast-feeding.
3. Prior history of thromboembolic events such as myocardial infarction, angina, cerebrovascular accident/TIA/stroke, pulmonary embolus or deep vein thrombosis.
4. History of heparin-induced thrombocytopenia and thrombosis (HITT or HIT type 2).
5. Active autoimmune disease. e.g. Crohn's disease, rheumatoid arthritis.
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10. Severe hypersensitivity (≥Grade 3) to ChAdOx1-containing vaccines and/or any of their excipients.
11. Prior administration of ChAdOx2 vaccine.
12. Severe allergy to eggs or any previous vaccination.
13. Current participation in another interventional cancer clinical trial involving the administration of an investigational medicinal product.

Date of first enrolment
01/06/2026

Date of final enrolment
31/03/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
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Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type

Funder Name
Cancer Research UK

Funder Name
CRIS Cancer Foundation

Alternative Name(s)
CRIS Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date