



## **Implementing and Evaluating Lung Cancer Screening for High-risk Hodgkin Lymphoma Survivors within the NHS National Lung Cancer Screening Programme**

Part of the **SEARCH** programme - **S**creening for **E**arly detection of second cancers **A**fter **R**adiotherapy and **C**hemotherapy for **H**odgkin lymphoma

**Chief Investigator:** Professor Kim Linton

**Ethics/IRAS number:** 357604

**You are being invited to participate in a research study because you previously received treatment for Hodgkin lymphoma, which may increase your risk of developing lung cancer.**

The study is testing a new risk calculator designed specifically for people with Hodgkin lymphoma to estimate the risk of getting lung cancer in the years ahead. If you are at risk, you will be invited to have a low-dose CT scan to check your lungs. This scan can help find lung cancer early, when it's easier to treat.

Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully before deciding whether to take part. You can discuss with others if you wish. Please ask if there is anything that is not clear or if you would like more information.

Thank you for taking the time to read this.

## About the research

### Who will conduct the research?

The SEARCH study is being delivered across England in collaboration with GP surgeries and Cancer Alliances, as a research study within the NHS National Lung Cancer Screening Programme.

The study is funded by NHS England and the NIHR Manchester Biomedical Research Centre. It is led by Professor Kim Linton at The University of Manchester. The University of Manchester is the study sponsor.

Collaborating institutions are:

- The Christie NHS Foundation Trust
- Health Innovation Manchester
- University of York
- University of Sheffield
- The University of Oxford
- University of Southampton

### What is the purpose of the research?

People treated for Hodgkin lymphoma have a higher chance of getting lung cancer than the average person in the general population.

Lung cancer screening saves lives in people who have smoked by diagnosing lung cancer at an early stage, when it is not causing symptoms.

The screening test for lung cancer is a 'low-dose CT scan' of the chest (thorax).

There is an existing NHS lung cancer screening programme in England for people who smoke or have smoked, but most people treated for Hodgkin lymphoma will not be selected. This is because the calculators used to assess lung cancer risk in the general population are not suitable for people treated for Hodgkin lymphoma.

In this study, we will use a **new lung cancer risk calculator** to select people treated for Hodgkin lymphoma to have a low-dose CT scan of the chest. The new calculator is designed specifically for people treated for Hodgkin lymphoma.

You have been selected for the study because your GP records show that you were treated for Hodgkin lymphoma and you have smoked or currently smoke. Alternatively, you may have been referred by your specialist or self-referred having heard about the study.

We are aiming to use the new calculator to select 500 people treated for Hodgkin lymphoma and offer them a lung cancer screening low dose CT scan.

The study will run for two years, from 2026 to 2028.

## Am I suitable to take part?

To take part in the study you must:

- Be between 45 and 74 years of age
- Have a previous diagnosis of Hodgkin lymphoma that was last treated at least 3 years ago and has not come back in that time
- Have smoked in the past or still smoke
- Be physically able to undergo a low-dose CT scan (you can read more about what this involves below)
- Be fit enough to undergo curative treatment for lung cancer, including chest surgery if diagnosed with early stage disease suitable for surgical management

You must not:

- Be very unwell from another medical condition
- Have ever been diagnosed with mesothelioma
- Already have a diagnosis of lung cancer unless this was made within the last 2 years after a screening test in the NHS Lung Cancer Screening Programme (if this applies to you, you can read more about what this involves below)

## Will the outcomes of the research be published or shared?

The results of the study will be published in medical journals, presented at conferences and shared with patient organisations like Lymphoma Action. Publications or presentations will not contain identifiable data about study participants.

Participants can opt to be informed of the study findings.

Data from this study may be shared with other researchers for use in future ethically approved research. Data sharing will not include any participant identifiable information.

Results of this study will help NHS England decide whether Hodgkin Lymphoma survivors should in future be invited to the NHS National Lung Cancer Screening Programme.

## Who has reviewed the research project?

The study was reviewed and approved by REC A Research and Ethics Committees Northern Ireland and the Medicines and Healthcare products Regulatory Agency (MHRA).

## Who is funding the research project?

This study is funded by the NHS England Small Business Research Initiative for Healthcare (SBRI) and the Manchester NIHR Biomedical Research Centre.

## What would I be asked to do if I took part?

### 1. Telephone call with a member of staff from the NHS lung cancer screening programme

You will initially receive a text message inviting you to take part. This message will include links to more information, including this information sheet and a short patient video.

If you “opt in”, a nurse will speak to you over the phone. They will ask questions about your health and smoking history. Your responses will help determine whether you’re eligible to join the study. If you currently smoke, support to help you quit will be available if you want this.

If you are eligible to take part, you’ll be offered an appointment for a lung health check to assess your risk of lung cancer.

Before this appointment, you will be sent a booklet (by post or email), to tell you more about lung health checks and help you decide whether to have a low dose CT scan if this is recommended.

Before the lung health check takes place, you’ll be asked to sign a consent form. Consent may be taken in person, or using e-consent, depending on what is most convenient for you.

- A trained member of the study team - usually a research or lung health check nurse - will explain the study to you, answer any questions you may have, and check that you have had enough time to read this information sheet.
- If you choose to use e-consent, you will be sent a secure online link where you can read the consent form and sign it electronically. You can still contact the study team at any time if you would like to discuss anything before signing. The study team will only proceed once they are satisfied that you understand what the study involves.
- You will be given a copy of your consent form to keep. Consent is an ongoing process - you can ask questions at any time and you can withdraw from the study whenever you wish, without giving a reason.

You’ll also be asked for permission to use your data in the study, even if you’re not eligible or decide not to participate. This includes information from your primary care records and anything you’ve shared up to that point.

### 2. Lung health check

The lung health check will be carried out by a specialist lung health check nurse. Depending on where you live, this may take place over the phone or in person at a special mobile clinic in a community location close to where you live.

The lung health check involves finding out about your lung health and collecting information to calculate your lung cancer risk.

- Your risk of lung cancer is calculated based on your age, smoking history and other medical history, including the age you were when diagnosed with Hodgkin Lymphoma.
- Your risk is calculated using the new risk calculator specially designed for Hodgkin Lymphoma survivors as well as the usual risk calculators used in the NHS Lung Cancer Screening Programme, so that we can compare results.

**If you are at low risk**, you will not proceed further with the study. However, we will ask for your consent to retain some of your personal data, so that we can contact you in future to reassess your risk if this is felt to be appropriate.

Even if you are currently assessed as low risk, your risk of developing lung cancer may increase over time, especially if you continue to smoke. We strongly encourage you to take up the offer of support to help you to quit smoking. If you notice any symptoms that could be linked to lung cancer, such as a persistent or worsening cough, coughing up blood, breathlessness, chest pain, unexplained tiredness, or weight loss, please speak to your GP. It's important to be aware that early-stage lung cancer often causes no symptoms at all. You may become eligible for screening in the future through the NHS Lung Cancer Screening Programme.

**If you are found to be at increased risk** of lung cancer using any of the calculators and want to continue in the study, you will be offered an appointment to have a low dose CT scan.

If you have had a low dose CT scan in the past 2 years, we may be able to use results of this scan, and any follow-up scans you had relating to this. If this applies to you, you will not need to have another scan.

If you had a low dose CT scan in the past 2 years and were diagnosed with lung cancer, you may still participate in this study if you want to and are well enough. This is to check if the new risk calculator correctly estimated your risk.

### **3. Low dose CT scan**

The low-dose CT scan can be done at a mobile clinic or at the hospital, depending on where you live, and may be done on the same day as your lung health check or at a later date. Mobile clinics are often conveniently located in supermarket car parks. You can bring someone else to this appointment.

The CT scan takes around 20 seconds to complete. For the scan, you do not need to have an injection of contrast. You do not need to take your clothes off, but you should avoid wearing metal such as zips, or jewellery, as these will need to be taken off.

At your scan appointment, you will have the option of providing a small sample of saliva for research purposes. Collecting the sample simply involves spitting into a tube. The sample will be sent for testing at The University of Manchester, where researchers will use your DNA to look for genetic patterns that may help improve future lung cancer risk calculators.

Testing your saliva cannot diagnose you with lung cancer or any other cancer and cannot accurately predict your risk of cancer in the future. We will ask you for written permission to share your saliva analysis results with researchers for future research. Participation in this part of the study is entirely optional and does not affect your participation in the other parts of the study.

There will be a Patient Reported Outcomes (PRO) questionnaire to complete before the CT scan takes place. This is to find out whether you have any symptoms relating to your lungs, your quality of life and your anxiety and worry levels. This will take between 10-20 minutes to complete. The PRO tools are available online or in paper format.

#### **4. After the low dose CT scan**

**You will only have one CT scan as part of this study. This is called your baseline scan.**

After your baseline scan, a specialist doctor called a radiologist will review the images and send a report to the study team and your GP. You will receive your results within four weeks.

Most people have a normal baseline scan and do not need any further tests. If this scan shows something abnormal, you will be contacted by phone to arrange an appointment at the hospital. There, you will meet with a specialist doctor who may recommend additional tests. Some of these tests can be invasive and carry their own risks, which the hospital team will explain to you in detail if needed.

Any further scans or investigations after your baseline scan, including future invitations to screening if you are eligible, will be done within routine NHS care.

You will be asked to complete more PRO questionnaires after your scan - at 3 months and at 6 months or the end of the study, whichever comes sooner. These can be completed online or by post, and you will be notified when this needs to be done. The 3 month questionnaire will take between 6-12 minutes to complete and the 6-month questionnaire between 8-15 minutes. The questionnaires will capture your experience and views to help us understand your quality of life and any anxiety or worry related to cancer, as well as your feedback about screening.

Your participation in this study will last for approximately 12 months.

You will be asked to agree to the collection of your scan results, even if these only become available after the study ends. This will ensure that we have a complete picture of your screening outcomes for the study analysis.

After your low-dose CT lung screening scan, we would like to know whether you experienced any complications on the day of the test. This includes events that were life-threatening, required you to be admitted to hospital, caused a significant or lasting disability, or any other medical issue that you felt was important. If you did experience a complication, please describe what happened, including when the problem began, when it resolved (if it has), and whether it is still ongoing.

Please send this information in an email to [SearchTrial@securemail.soton.ac.uk](mailto:SearchTrial@securemail.soton.ac.uk). This is a secure email address.

## What are the possible risks and disadvantages of taking part?

### ➤ **Low-dose CT scan (LDCT)**

If you take part in this study, you will have one low dose chest CT scan. You would not have received this scan if you did not take part. These procedures use ionising radiation to form images of your body and provide your doctor with other clinical information. Ionising radiation may cause cancer many years or decades after the exposure.

CT scans are delivered under NHS Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) and follow the NHS Lung Cancer Screening Programme standards.

### ➤ **False positives and false negatives**

CT scans can sometimes show an abnormality that is not cancer (a false positive). This may lead to further scans or tests such as a PET-CT scan, bronchoscopy or biopsy. These follow-up tests may involve discomfort or small risks such as bleeding or infection. CT scans may also rarely miss a cancer (a false negative).

### ➤ **Incidental findings**

CT scans may detect findings unrelated to lung cancer (for example, heart, thyroid or liver changes). These usually do not cause harm but sometimes require follow-up in routine NHS care. The NHS Lung Cancer Screening Programme has national pathways for managing these findings.

### ➤ **Psychological impact**

Some people experience worry before or after a scan, or while waiting for results. If you have further tests, you may also experience uncertainty or anxiety.

### ➤ **Risks related to the new risk calculator**

The risk calculator being tested in this study is investigational. Although it has been validated and tested, there remains a small possibility that your lung cancer risk could be over-estimated or under-estimated. This could mean being offered a scan you may not need, or not being offered a scan when you might benefit from one. These risks are reduced by using several different lung-cancer risk models as part of the NHS Lung Cancer Screening Programme.

### ➤ **System or data-related risks**

As with any digital system, there is a small possibility of system errors, incorrect data entry, or temporary technical failure. These risks are reduced through validation checks, audit trails, user training and NHS information-governance procedures.

➤ **Risks from follow-up investigations (if needed)**

If the CT scan suggests further investigation, this may involve additional imaging or procedures. These can carry small medical risks, which will be fully explained by your NHS clinical team if they become relevant.

➤ **Risks not related to the research**

Most of the risks described above relate to the clinical part of lung cancer screening rather than the research itself. The research does not add extra radiation, additional scans, or additional procedures beyond what is standard in the NHS Lung Cancer Screening Programme.

### **Will I be compensated for taking part?**

You will not be compensated for taking part in this study. **If your local lung cancer screening centre or mobile screening unit is not within your usual healthcare area, you may be able to apply for a travel allowance to help cover the additional distance to attend your lung health check or scan.**

### **What happens if I do not want to take part or if I change my mind?**

It is up to you to decide whether to take part or not. If you do decide to take part, you will be given this information sheet to keep and asked to sign a consent form before your lung health check.

If you don't wish to take part, please simply respond to the text message invitation with an opt-out. You don't need to give a reason, and this will not affect your care in any way. However, to help us understand why some people choose not to participate, you will be invited to provide optional feedback. You may also choose to share your contact details so that a member of the SEARCH study team can follow up with you about your decision. This is entirely voluntary.

If you decide to take part, you are still free to withdraw at any time without giving a reason and without detriment to yourself. If you withdraw from the SEARCH study, you will no longer take part in any study-related activities, and we will not collect any further data from you. However, any data and (if relevant) samples that have already been collected will be used for analysis as described in this Participant Information Sheet and the Informed Consent Form.

## Data Protection and Confidentiality

- **How will we use information about you?**

We will need to use information from **you** for this research project. This information will be obtained from your medical records. This information will include your:

- Name
- Date of birth
- Postcode
- Phone number
- NHS number
- Ethnicity
- Consent
- Medical history
- Saliva samples (optional)

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

The University of Manchester is the sponsor of this research. We will share your information related to this research project with the following types of organisations:

- **Southampton Clinical Trials Unit (SEARCH database)**

We will keep all information about you safe and secure by:

- Participant data will be entered onto and stored in the specific SEARCH database, built and hosted by Southampton Clinical Trials Unit.
- People will use this information to do the research or to check your records to make sure that the research is being done properly.
- People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.
- Your personal information will only be looked at by NHS and lung cancer screening staff to contact you about the study and record your results. You will be asked for your permission for this.

We may share or provide access to data about you outside the UK for research related purposes to:

- **SEARCH Medidata RAVE database servers held in the US**

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to

identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- Database provider

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- Medidata has a EU-U.S. Data Privacy Framework Privacy Policy in place which meets requirements in line with GPDR

- **How will we use information about you after the study ends?**

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 25 years. The study data will then be fully anonymised and securely archived or destroyed.

- **What are your choices about how your information is used?**

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

- **Where can you find out more about how your information is used?**

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK:

- our leaflet [Privacy Notice for Research](#) and [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch)
- by asking one of the research team
- by sending an email to [dataprotection@manchester.ac.uk](mailto:dataprotection@manchester.ac.uk) or
- by ringing us on 0161 275 7789

### **What if I have a complaint?**

#### **Contact details for complaints**

If you have a complaint that you wish to direct to the research team	Please contact: <b>The SEARCH study management group, c/o Dr Joanna Williams, The University of Manchester, Oxford Road, Manchester M13 9PL</b>
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	Email: <a href="mailto:SEARCH_lung@manchester.ac.uk">SEARCH_lung@manchester.ac.uk</a>
If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers, in the first instance	Please contact: <b>The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL</b> Email: <a href="mailto:research.complaints@manchester.ac.uk">research.complaints@manchester.ac.uk</a> Telephone: 0161 306 8089
If you wish to contact us about your data protection rights	Please email: <a href="mailto:dataprotection@manchester.ac.uk">dataprotection@manchester.ac.uk</a> Or write to: <b>The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University</b> They will guide you through the process of exercising your rights.
You also have a right to complain to the Information Commissioner's Office about complaints relating to your personal identifiable information	Please contact: <b>Information Commissioner's Office</b> URL: <a href="https://ico.org.uk/make-a-complaint/">https://ico.org.uk/make-a-complaint/</a> Telephone: 0303 123 1113

### Where can I get support if I need it?

Taking part in a lung cancer screening study can sometimes feel worrying, particularly while waiting for results or dealing with health concerns. If you would like independent emotional support or information about lymphoma, you can contact Lymphoma Action, the UK charity for people affected by lymphoma. Lymphoma Action is also a partner organisation in this study.

#### Contact Details

If you have any questions or concerns about the study, please contact the local principal investigator at your site	<Name of local principal investigator> <ul style="list-style-type: none"> <li>• &lt;phone number&gt;</li> <li>• <a href="#">&lt;email address&gt;</a></li> </ul>
If you have been referred by your hospital doctor or have self-referred and haven't yet received a text	<b>Sara Waplington</b> <b>Clinical Trials Manager</b>

<p>message inviting you to the study, please contact Sara Waplinton at The Manchester NHS Foundation Trust.</p>	<ul style="list-style-type: none"> <li>• <a href="mailto:SEARCHStudy@mft.nhs.uk">SEARCHStudy@mft.nhs.uk</a></li> </ul> <p>Her team will refer you to the closest study site to where you live.</p>
<p>You may also contact the SEARCH study team directly</p>	<p><b>Dr Joanna Williams</b>  <b>SEARCH project manager</b></p> <ul style="list-style-type: none"> <li>• <a href="mailto:SEARCH_lung@manchester.ac.uk">SEARCH_lung@manchester.ac.uk</a></li> </ul>
<p>You may contact Lymphoma Action for independent support</p>	<p><b>Lymphoma Action</b></p> <ul style="list-style-type: none"> <li>• <b>Helpline: 0808 808 5555 (freephone, 10am–3pm, Monday–Friday)</b></li> <li>• <b>Email: <a href="mailto:information@lymphoma-action.org.uk">information@lymphoma-action.org.uk</a></b></li> <li>• <b>Website: <a href="http://www.lymphoma-action.org.uk">www.lymphoma-action.org.uk</a></b></li> </ul>