EARLY LUNG CANCER DETECTION STUDY

WE NEED 10,000 PEOPLE FROM TAYSIDE & GLASGOW TO TAKE PART
Lung cancer kills more people than any other cancer. In Scotland, 5000 people die from lung cancer every year. This is because most cases are picked up late when the chance of cure is low. This is often because there are few symptoms until the cancer has been growing for a long time. A new blood test called EarlyCDT-Lung might be able to pick up very small lung cancers before they cause health problems. We want to find out if earlier detection may help save lives in the long term by following everyone who takes part for up to 10 years. We also want to know what people think about the test so that a decision can be made about whether to offer it as a nationwide lung cancer screening test. By taking part you can help us to find this out.

The ECLS Study are inviting 10,000 people from Tayside, Glasgow and the surrounding areas to take part. These regions have been chosen because we know that lung cancer is more common in these areas.

People who are at higher risk of developing lung cancer will be invited to take part by either their GP or from community based programmes. Those who agree to take part will either receive an EarlyCDT-Lung Test or be followed up by usual care. Based on what we already know about the test we expect that 400-450 participants will have a positive test result. These people will be offered a chest X-ray and a series of CT scans over 2 years. All participants requiring further investigations or treatment will be treated within NHS guidelines.

We hope that you can join us in this important lung cancer screening study.

The ECLS team
Please read this booklet and think about whether you would like to take part. Talk about it with family and friends. Ask us if there is anything that is not clear or you would like more information about.

The main points to the study are:

- 10,000 people will be invited to take part in the study from Tayside, Glasgow and the surrounding areas. These areas have been chosen because we know that lung cancer is more common in these areas.

- Half of those taking part will be offered the new blood test and have a consultation with a specially trained research nurse to discuss the results (lung cancer test group). The other half (non-test group) will also have their blood taken, but it will not be tested as part of this study. It can, however, be used for other cancer related medical research if you agree to this.

- People who have a positive lung cancer blood test will get a chest X-ray and a lung scan and 6 monthly scans for 2 years. If needed, they will be referred to a specialist lung consultant. People with a negative lung cancer blood test and those in the non-test group will be monitored by their GP as normal.

- We will ask some people in each group to tell us about their health and their thoughts about having the test.
You may be able to take part in the ECLS Study if you:

• are aged between 50 – 75
• are a smoker or ex-smoker

We are doing this study to answer these two questions:

• Will this test help save lives?
• What do patients think about the test?

**Why are we doing the study?**

Lung cancer kills more people than any other kind of cancer. It is more common in Scotland than the rest of the UK, with about 5000 new cases each year. Lung cancer is often found too late for treatment to be useful. This reduces the chance of surviving. When found early, 6 out of 10 people will still be alive 5 years later. When found late, only 1 out of 100 people will still be alive 5 years later.

There is now a new blood test that we think will help find lung cancer earlier.

When we get cancer, our bodies fight it by making chemicals against the cancer. These chemicals can be measured in blood even when the cancer is very, very small. This means that if we measure these chemicals in the blood, we can find out if someone has lung cancer before they start to feel unwell and can also start treating the cancer sooner. The test is only looking for lung cancer, so will not pick up other types of cancer or other diseases.
STUDY INFORMATION

Why have I been asked to take part?

Lung cancer can happen to anyone, including the young and old and people who do not smoke, but the risk is higher in those over 50 and those who have smoked.

For these reasons, we are asking people to take part if they are:

• aged between 50 and 75 and who are smokers or ex-smokers; or are
• aged between 50 and 75 and who have had a close relative (mother, father, brother, sister) with lung cancer.

A small number of people will not be able to take part in the study.

This includes people who:

• have previously had a cancer
• have been coughing up blood or have lost weight without dieting
• would be too ill to have an operation if they were found to have lung cancer
• are not able to decide for themselves if they want to take part in the study

Do I have to take part?

No, it’s up to you. We will go through the information about the study with you and if you decide to take part we will ask you to sign a consent form saying that you are happy to take part in the study. If you do take part you can change your mind later and you do not have to tell us why. It won’t make a difference to the usual care you get from your doctor.

How the research works

Whenever a new test is developed we need to find out if it works. We do this by having a group of people who have the test and a group of people who do not. Both groups need to be similar so that we can compare what happens to the people in each group. To try and make sure both groups are the same, each person is put into a group at random. This is done by a computer putting people into one of the two groups by chance. It is the fairest way of deciding who gets the test and means everyone will have a 50/50 chance of being put in either group. This means that you are not chosen to be in a group for any particular reason.
WHAT WILL HAPPEN TO ME IF I TAKE PART?

You will be randomly put into one of two groups. The two groups will be:

**TEST GROUP**
This group will have the new blood test and will be told the result within 4 weeks of having their blood taken.

**NON TEST GROUP**
This group will have blood taken but it will not be tested as part of this study. It may be used for other cancer related medical research if you agree to this.

When you arrive for your visit you will be seen by a research nurse. At the meeting the nurse will explain the study to you and answer any questions you may have. The meeting is likely to last about 30-45 minutes or longer if you need more time.

At the meeting you will:
- be asked to consent to taking part
- be asked some questions about yourself and your health
- have a small sample of blood (about 2 teaspoons) taken from your arm
- be asked to fill in a survey questionnaire asking about your health and thoughts about tests for lung cancer before you know whether you are in the lung cancer test group or the non-test group. This will take about 10 minutes to complete, the nurse can help you complete it. You do not have to fill in this survey if you do not want to.
- be told whether you are in the lung cancer test group or the non-test group
People in the non-test group are still playing a very valuable role in the research by allowing a comparison with those whose blood is tested, and could also be helping future generations.

ECLS Team
TEST GROUP

If you are in the lung cancer test group you will be sent your results by post within 4 weeks of having the test.

If your test is negative and you would like to talk to the research nurse about your results, we can arrange for you to have a telephone call or an appointment to do this.

If your test is positive you will be asked to call to make an appointment, as soon as possible, with the research nurse to discuss what happens next.

We will track what happens to everyone in the study for 10 years to see if anyone gets cancer, using information from the Scottish Cancer Registry. This contains details for everyone who gets cancer about the type of cancer and the treatment they have had. This follow up does not mean any further study visits.

We might wish to contact you about possible future participation in research but this would be a new approach without obligation.

NEGATIVE BLOOD TEST
This means it is very unlikely you have lung cancer at the moment. Between 98 and 99 out of every 100 people with a negative test do NOT have lung cancer at that time.

POSITIVE BLOOD TEST
This does not mean you definitely have lung cancer. Only 1 in 9 people with a positive test is likely to develop lung cancer within the next 2 years.
NEGATIVE BLOOD TEST

This means it is very unlikely you have lung cancer at the moment. Between 98 and 99 out of every 100 people with a negative test do not have lung cancer at that time.

If you have a negative test:

• A negative test does not mean you will never get lung cancer. It is important that you see your GP if you feel unwell in any way that could be due to lung cancer, even if this happens soon after your negative test. This includes persistent cough, coughing up blood, shortness of breath, weight loss or loss of appetite.

• If you agree, we might ask you to fill in a short survey at 1 and 3 months after your test results then 6 monthly for 1 year to ask about your health and thoughts about the blood test. The survey will take about 15 minutes to fill in, but not everybody will be asked to do this.

• It is important to remember that this test is only for lung cancer, so you should carry on having tests for other types of cancer if they are offered to you (e.g. bowel cancer test, mammograms, cervical smears).

no further study visits
This does not mean you definitely have lung cancer. Only 1 in 9 people with a positive test is likely to develop lung cancer within the next 2 years.

If your test is positive:

• You will be offered a chest X-ray and a lung scan (also called a CT scan). The results of these will be sent to your GP and your local specialist chest consultant who is helping with the study. If the X-ray or lung scans suggest further investigations are required, you will be offered an appointment with your local specialist chest consultant.

• If you have had a chest X-ray or a relevant CT scan in the previous 3 months we will review these and proceed as clinically appropriate.

• If there are no problems found on the lung scan, you will be sent a letter explaining this and you will be offered lung scans every 6 months for the next 2 years. About 2-4 days before each of your CT appointment dates, a member of the research team will give you a call and ask you a few questions about your health and discuss travel arrangements.

• If you agree, we might ask you to fill in a short survey 1 month and 3 months after your test results, then every 6 months for 2 years after your scan results are known. This survey will ask about your health and thoughts about the blood and other tests. The survey will take about 15 minutes to fill in, but not everybody will be asked to do this.

• It is important to remember that this test is only for lung cancer, so you should carry on having tests for other types of cancer if they are offered to you (e.g. bowel cancer test, mammograms, cervical smears).
What are the benefits of taking part?

If you are in the lung cancer test group and you have lung cancer this may be picked up more quickly than it would have been if you were not taking part in the study. This could mean that the cancer is more treatable and the chance of surviving is better. If you are in the non-test group, the information you give us will be really important in helping us find out if the new lung cancer blood test works, by comparing what happens to both groups. By taking part, you are playing an essential role in the research and could be helping future generations.

Are there any disadvantages or risks of taking part in the research?

Blood Sample: The blood test will be taken in the same way as other blood tests are usually taken, using a small needle. It may be uncomfortable but this should not be any worse than other blood tests you have had.

Feeling Anxious or Worried: Some people may worry about what their test result will be. Getting a positive test result and waiting for results of chest X-rays and lung scans may cause people to worry. On the other hand, people might worry more if they found out they had lung cancer at a late stage when the chance of surviving is much lower. We will be looking at whether people worry about having blood and other tests as part of the study.

False Positives and False Negatives: No medical test is completely accurate. This blood test is expected to pick up about 40 in 100 cases of lung cancer and detect the cancer at an early stage. However this means it doesn’t pick up all cases of lung cancer (false negative). So even if your test is negative, or if you are in the non-test group, it is important that you see your GP if you are unwell in any way that could be due to lung cancer. This includes persistent cough, coughing up blood, shortness of breath, weight loss or loss of appetite.

As no medical test is completely accurate, the blood test will be positive in some people who do not have early lung cancer (false positive). These people will be offered a chest X-ray and lung scans to see if they have lung cancer. We expect this to happen to 8 out of every 9 people who have a positive test result.
CHEST X-RAYS & CT SCANS

Chest X-rays and lung scans use radiation. People can develop cancer because of this type of radiation, but this is very rare. The amount of radiation you get from a chest X-ray is very small. About 1 million people would need to have a chest X-ray for 1 extra person to develop cancer because of the chest X-ray. A CT lung scan gives about 600 times as much radiation as a chest X-ray. Approximately 1500 people would need to have a CT lung scan for one extra person to develop cancer because of the scan.

If you have a positive blood test and have the chest X-ray and all five scans over the 2 years of the study, the additional risk that you might undergo is of the order of 1 in 330.

These risks are small compared to the one in four chance we each have of developing cancer in our lifetime.

You should bear in mind that you will experience some exposure up to this maximum, because of your participation in this study, even when you do not have lung cancer and have no treatment. The research team, and independent experts who have reviewed the study design, consider that the design is justifiable (a) for the early warning that it might provide to those who do have lung cancer, and (b) for the substantial benefit to society that might be provided in future by adoption of the test.
Incidental Findings

When your chest X-ray and CT scans are reviewed there is a possibility that an abnormality other than lung cancer will be detected. These abnormalities are known as incidental findings. If the abnormality requires further assessment or medical follow-up we will contact you, and with your consent your GP, and make any referral required for further investigation. The necessary steps would be taken for you to be treated according to current clinical practice.

There is a possibility that the abnormality is a false alarm.

Before taking part you should think about whether a positive blood test might affect any insurance you have, or may plan to get in the future. You should seek advice about this if necessary.

What will happen if you don’t want to carry on with the study?

You can leave the study at any time without having to tell us why. If you do leave the study, the usual care you receive from your doctor will not be affected in any way. You can withdraw from future involvement (no more visits or contacts) but allow us to continue to use data you have already provided (completed forms, completed questionnaires, blood samples) and allow us to use information about you from the Scottish Cancer Registry and your medical records; or you can withdraw completely (no more visits or contacts, all data already provided is destroyed and there will be no reference to the Scottish Cancer Registry or your medical records).

Will the information I provide be passed on to anybody else?

We will let your GP know you are taking part in the study and they will be sent the results of your blood test. Your GP and the local specialist lung consultant who is helping with the study will also be sent the results of your X-rays and lung scans.
What happens when the research stops?
If you are being followed up by the lung specialist because you have had a positive test, you will continue to be followed up directly for 2 years after the test and then for a further 8 years through records.

How will my information be stored?
All information we collect about you will be kept strictly confidential. Information will be stored securely under conditions in keeping with the Data Protection Act 1998. The chest X-ray and CT scan images will be stored indefinitely using your name and unique hospital record number within the NHS clinical system and can be made available to specialist doctors for your future health care needs. The other data we collect about you will be stored using a unique study code from which you cannot be identified and held on password protected University of Dundee secure databases. Only individuals directly involved with the study, including researchers from the Universities of Dundee, Strathclyde, Glasgow and Nottingham, the Tayside Clinical Trials Unit and NHS Greater Glasgow and Clyde and NHS Tayside will have access to this information.

Where information is transferred to these researchers, it will be held on password protected secure databases within their organisations.

Reports or publications of research findings will not contain information through which you can be identified. Authorised people from the University of Dundee and NHS Tayside, whose role is to check that research is properly conducted and the interests of those taking part are protected, can see the information we hold about you, but they are not allowed to pass your information onto other people. We will keep your information for 20 years after the end of the study. We will make sure all information that you could be recognised from is destroyed as soon as we no longer need to contact you.
What if I develop lung cancer?

If you are found to have lung cancer at any time during the study period all the necessary steps would be taken for you to be treated according to current clinical practice. You will also have access to the research nurse to discuss your diagnosis.

What will happen to the results of the study?

If you would like to know what we find, we can send you the results at the end of the study in 2016. We will send our results to Government departments, organisations that look after people with cancer and other patient groups. We will publish our findings in scientific journals and present them at scientific meetings. It will not be possible to identify you in the published results.

What will happen to my blood sample?

If you are in the lung cancer test group your blood sample will be sent to the USA for analysis as the test is not currently available in the UK. Your blood sample will be identified by a barcode, so you can’t be identified from it. The results will be sent back to the study team who will write to you with your results. In the unlikely event that your blood sample is lost in the post you will be contacted and an appointment will be arranged to have another sample taken. Part of your blood sample will also be stored and may be used for other cancer related medical research in the future if you agree to this.

For the non-test group, your blood sample will be stored and may be used for other cancer related medical research in the future if you agree to this. If we share your blood samples with other researchers, some of whom may be outside the European Union, these are labelled using a barcode so you can not be identified. All blood samples will be stored for up to 20 years at the University of Nottingham.

Any research using your blood samples will be subject to proper scientific and ethical review. By agreeing to your blood sample(s) being used in this way you are agreeing that any findings from the research on your blood sample are owned by the institutions carrying out the research. Occasionally a research finding can lead to developments that have a commercial value. If this happened the rights for these developments would belong to the institutions carrying out the research, which would be free to enter into contracts.
What if there is a problem with the study?

If you have any questions or worries about the study you can talk to us about it. Our names and phone numbers are given below. If you believe that you have been harmed in any way by taking part in this study, you have the right to make a complaint and seek any resulting compensation through the University of Dundee and NHS Tayside who are acting as the research sponsor.

If you have a complaint you can contact an independent adviser, Professor David Weller on 0131 650 2807.

As a patient of the NHS, you have the right to pursue a complaint through the usual NHS process. To do so, you can make a written complaint to the Complaints and Claims Manager, Complaints and Advice Team, Level 9 Ninewells Hospital, Dundee, DD1 9SY. Freephone: 0800 027 5507. If something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for legal action against NHS Tayside. You may have to pay your legal costs.

Will I get paid for taking part?

If you are asked to fill in surveys after the blood test, then to thank you for your time, you will receive a £5 gift voucher for each survey you fill in. You can spend this voucher in local shops.

Travel expenses

Reasonable travel expenses can be reimbursed.

Who is paying for this study?

The study is paid for by the Scottish Government and Oncimmune, the company who developed the new blood test.

Who has reviewed this study?

The East of Scotland Research Ethics Committee REC 1, which has responsibility for scrutinising all proposals for medical research on humans in Tayside, has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your records in this research, together with any relevant records, be made available for scrutiny by monitors from the University of Dundee and NHS Tayside, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

Who is doing this study?

The study is being done by researchers from the Universities of Dundee, Strathclyde, Glasgow and Nottingham, the Tayside Clinical Trials Unit and NHS Greater Glasgow and Clyde and NHS Tayside.
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