Participant Information Sheet

Study title:

'Better tests' – improving diagnostic accuracy and prognostication in Interstitial Lung Diseases

Study Researcher: Dr Mark Spears

We are inviting you to take part in a research study

Before you choose whether or not to take part, we want you to understand why we are doing the study. We also want to tell you what it will involve if you agree to take part.

Please take time to read this information carefully. You can ask us any questions you have and talk to other people about it if you want. We will do our best to answer your questions and give you any more information you ask for. You do not have to decide straight away.

Why are we doing this study?

Currently doctors are unable to accurately predict what will happen to patients with a group of chest conditions, known as 'interstitial lung diseases' (ILD for short), after their detection. This is due to doctors planning ongoing care based on CT scans, and some blood tests, with both having recognised weaknesses. For example, CT scans can be interpreted very differently by different doctors, causing variation in diagnoses and treatment plans.

Similarly, current blood tests can make doctors think patients have their condition due to what may be innocent exposures, such as birds, or something in their home or work. This can lead to patients being strongly counselled to stop undertaking a sport such as Pigeon Fancying, undertaking significant home renovations or changing their place of work to no benefit.

Finally, some strong anti-inflammatory treatments for ILD are provided by doctors based on these tests (CT and blood tests), with doctors only knowing if they have been useful once improvement has taken place. This results in variation in expectations about responses to treatment and prognosis. All of this is clearly unsatisfactory.

What is being tested?

There are several potentially useful blood and breathing tests that could be employed in patients with ILD. We will examine some of these, as available, for their acceptability to patients and ease of use by doctors. The results obtained will be assessed for their ability to predict what happens next, with respect to patients' ILD behaviour and their response to any treatments given. This will allow their use in larger studies, and in time, for the tests that show the best performance, their regular use in routine clinical care.

Why have I been contacted?

You have been approached either because you are known to have an ILD, or are from a group with an increased risk for developing ILD e.g. you are a Pigeon Fancier (and have increased risk through regular exposure to Pigeon bloom, if standard protective measures are not taken).

Do I have to take part?

No. It is up to you to choose. Taking part in this study is entirely up to you. You can choose to take part or choose not to take part. If you choose to take part you can also stop taking part in the study at any time. You do not have to give a reason for not taking part or for stopping. If you do not want to take part, or want to stop the study, the medical care you get and your relationship with the medical or nursing staff looking after you will not be affected.

What will happen to me if I take part?

Taking part will involve:

1. Your providing informed consent. This will involve you considering the information contained in this information sheet, asking questions about what will be involved, and completing a consent form with a member of the research team, which formally records your decision to take part.
2. A short interview about your general health, your lung health, how breathless you are during normal activity, your pigeon keeping (if appropriate) or other bird exposure, work exposures and home life. This will be completed with a member of the study team.
3. Measurement of your height and weight.
4. Measurement of your breathing (a forced breathing test called spirometry, which will involve breathing out as fast and for as long as possible, for up to eight times (with coaching on how to do the test, and rests between attempts)) when wearing a nose clip.
5. A further breathing test, called oscillometry, again when wearing a nose clip. This will involve you breathing normally into a tube for a short period (the test is complete once you have performed ten acceptable breaths) when a sound wave is applied.
6. A further breathing test, which will again involve you breathing normally into a collection device for a short period, to enable collection of chemicals in your breath that may be of relevance to lung health.
7. A small blood sample (about 7 teaspoons).
8. In a small number of Pigeon Fanciers, when appropriate to assess the test under examination, we will ask if you can perform a breathing and/or blood test before and after exposure to your pigeons.

These steps will be undertaken with a qualified doctor, phlebotomist, respiratory physiologist or nurse as appropriate.

When completing the short interview we will ask if you have been referred to a consultant in a hospital about your lung health. If you answer yes, we will ask for the name of your GP, consultant and hospital, and for your permission to contact them directly. We will then contact them to ask for further information from your medical notes including blood tests, lung function testing, CT scans and reports and outcome of any 'multi-disciplinary team' meetings. This will enable us to identify the nature of your referral, work up and the final diagnosis obtained. This information will be used in the research to help us understand how good the tests are at detecting lung health.

We will also provide you with a copy of your consent form, and this leaflet, for your records.

If you attend clinics in NHS Tayside, we will regularly review your progress after you join the study via review of your notes and when you attend clinic. We will use this information to examine the usefulness of the tests employed. If new breathing or blood tests become available we will ask if you would be interested in performing these when you next attend clinic, and make arrangements for this to take place.

If you have joined the study via one of our recruitment events, such as the RPRA 'Show of the year' or the Scottish Homing Union meeting, we will contact you in writing each year. This will allow us to ask some simple questions about your lung health, ongoing exposures of relevance and whether these have changed. You will be asked to complete a simple form and then post this back using a supplied stamped addressed envelope. Again we will ask you to let us know if you have been referred to hospital for further assessments, and for who we should contact to obtain relevant information. You will be welcome to re-attend further recruitment events and to repeat the tests or perform any new ones as you wish.

Each time we contact you, we will provide you with a 'withdrawal form' along with a stamped addressed envelope. This will allow you to easily withdraw from the study, if this is desired, and can be completed by someone on your behalf.

If you are a Pigeon Fancier, we also need to understand the impact of recent exposure to your birds on some of the tests we are examining. This will be important for some of the test results that may be affected by the time since you were last with your Pigeons. A small number of Fanciers will be needed to help with this.

This additional testing will involve your performing the test before and after normal care for your birds. If this is of interest to you please let one of the team at the meeting know. You can also let Dr Spears know using the contact details provided in this leaflet, or on the annual contact letter. We will reach out to you when this additional testing is being undertaken. You do not need to do the additional testing to take part in the main study. You can also change your mind on doing additional testing at any time, just like the main study.

Will taking part in the study affect my usual care?

Taking part in this study will not affect your usual care. Your doctor will not change any treatments or undertake investigations different from how they would normally. In addition, any results generated will be anonymised and not made available to your clinician, to prevent their decision making being affected by the results. This is appropriate as all test results will be experimental, with their value in predicting events uncertain until completion of this and other research projects.

What will happen when the study finishes?

We expect the study to be open to new participants for up to 5 years, with a period of follow up 5 years. If the study is extended, we will write to you again to let you know and we will give you the option to continue in the study or to leave. On completion of the project we will publish the conclusions from the project, and any subsequent work, via relevant charities, such as Action for

Pulmonary Fibrosis and through associations such as the Scottish Homing Union and the Royal Pigeon Racing Association and through press releases from NHS Tayside and the University of Dundee.

What are the possible benefits of taking part?

Through taking part you may contribute to an increase in scientific knowledge about ILD and may help develop new tests that will be useful in routine clinical care.

Can I take part if I am already participating in another research study?

Usually you will be able to take part even if you are in another research study. We will ask you if you are in another study so that we can advise you accordingly and liaise with the other study team.

What are the possible disadvantages and risks of taking part?

There is a risk of minor discomfort and bruising from our taking the blood sample. One of the breathing tests (spirometry) can make some people dizzy, as it requires a forced breathing out. To get an accurate result for you, we may need to perform this test up to eight times. We will ask you to perform this test whilst seated and you will have a rest between each attempt to ensure you are able to repeat the test to the best of your ability. We will also ask you a series of questions about your health prior to measuring your breathing to make sure that you are well enough to take part.

During the study we may discover findings that suggest you have an undiagnosed condition through performing the required tests. If this occurs the study team physicians will discuss the findings with you and how you should proceed, which will usually involve you attending your GP. The study lead, Dr Spears, will also provide a letter to you outlining the findings, for you to share with your GP.

Who is organising and funding this research?

This study is being sponsored by NHS Tayside. Funding to support the project is provided by the British Pigeon Racing Medical Research group. We plan to seek additional funding from other research charities and major funders of medical research such as the MRC. The study is being organised by Dr Mark Spears, NHS Tayside.

What will happen with the information collected about me (and collected samples)?

All information which is collected about you during the study will be kept strictly confidential. The samples and data will be labelled by unique numbers rather than names. The link between the unique numbers and names will be held securely and separate.

Your blood and breath samples will be used to test for molecules that tell us about the risk for someone developing ILD or experiencing progression of their ILD, and the responses to any treatments. If you keep pigeons, we will also assess your immune system response to pigeon exposure and how this may relate to lung problems.

We ask your permission to store your samples for up to 10 years after the study completes, to allow further research to take place using techniques not available whilst the study is open to new people.

Any tests on these stored samples will only take place after we obtain the required approvals from the relevant authorities.

Your data, which includes the answers that you gave in the interview, your breathing test results and any medical results or reports that we obtain from your consultant or GP, will be analysed with the samples. The blood samples and relevant associated data will be stored securely on NHS Tayside premises using an anonymised study identifier and will be retained for 10 years after the study is fully recruited. We also ask for your permission to also use your stored blood samples for future studies by other qualified researchers, which will only take place after ethics review and approval of the proposed future research.

NHS Tayside is the sponsor for this study based in the United Kingdom. We will be using information obtained from you and from your medical records in order to undertake this study and they will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. NHS Tayside will keep identifiable information about you for one year after the study has finished.

Your rights to access, change or move your information once you enter the study are limited, as we need to manage your information in specific ways, so the research is reliable and accurate. If you withdraw from the study, we normally keep the information about you that we have already obtained. If you choose to stop taking part in the study, we would like to continue collecting information about your health from your GP/hospital records. If you do not want this to happen, tell us and we will stop. To safeguard your rights, we will use the minimum personally identifiable information possible.

You can find out more about how we use your information by contacting the Data Protection Officer for NHS Tayside. You can contact them by emailing or writing to:

- **Email**: tay.informationgovernance@nhs.scot
- **Address**: Maryfield House (South), 30 Mains Loan, Dundee, DD4 7BT

NHS Tayside will collect information from you and your medical records for this research study in accordance with our instructions. NHS Tayside will use your name, CHI/ or NHS number and contact details to contact you and your doctors (with your permission) about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study.

Individuals from NHS Tayside and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Your local NHS Trust or Health Board team will pass appropriate information to NHS Tayside along with the information collected from you and your medical records. The only people in NHS Tayside who will have access to information that identifies you will be people who need to contact you to audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, CHI/or NHS number or contact details.

NHS Tayside will collect information about you for research from your doctor, if you provide consent for us to do so. This information will include your name, CHI/ or NHS number, contact details and health information (such as previous diagnoses, tests and current medication), which is regarded as a special category of information. We will use this information in our study of pigeon lung and other interstitial lung diseases.

When you agree to take part in a research study, anonymised information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research**.**

The information we collect and publish will not allow people to identify you and will not be combined with other information in a way that could allow this. The information will only be used for the purpose of health and care research and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

For further information on how your information is used and protected see https://www.hra.nhs.uk/information-about-patients/

What will happen if I do not want to carry on taking part in the study?

You can withdraw at any time, by either sending us the withdrawal form that we will give you today, or when posted out in future years, or when we see you during your routine clinical care in NHS Tayside. You can also contact us using the details at the end of this document.

After you withdraw from the study we will keep information about you that we already have, unless you specifically ask for this to be deleted. There are several options outlined in the withdrawal form, explaining how we can approach this.

If you choose to stop taking part in the study, we will aim to continue collecting information about your health from your GP/hospital records given the potential importance to the study. If you do not want this to happen, tell us and we will stop.

Will I be reimbursed for taking part?

You will not be paid for taking part in this study.

How will we use information about you?

We will need to use information from you, your medical records, and potentially from your GP and your hospital consultant for this research project.

This information will include your:

- Name
- CHI/NHS number
- Contact details

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.

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.

NHS Tayside is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- Other NHS organisations e.g. researchers based in NHS trusts outwith Scotland
- Universities
- Commercial organisations developing tests relevant this project e.g. breath diagnostic machines or blood tests looking for markers of ILD
- Commercial organisations developing new treatments designed to treat ILD e.g. pharmaceutical companies

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

- Allow researchers to perform detailed analyses not possible if the data is withheld from them

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:

- Other healthcare organisations e.g. researchers based in hospitals outwith the UK
- Universities
- Commercial organisations developing tests relevant this project e.g. breath diagnostic machines or blood tests looking for markers of ILD
- Commercial organisations developing new treatments designed to treat ILD e.g. pharmaceutical companies

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

- Keeping all written information in locked cabinets in rooms within swipe card protected areas on NHS Tayside property

- Providing only anonymised data to collaborators e.g. data will be shared using only the number allocated to you in the study rather than data including your name, date of birth or address
- Only sharing the minimum information required for each collaboration
- Transferring of data will only take place using secure email or other electronic methods meeting the most stringent legislative requirements applicable

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 10 years after recruitment to the study is completed. 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 choose to stop taking part in the study, we would like to continue collecting information about your health from NHS records, given this will enable us to answer the research questions. If you do not want this to happen, tell us and we will stop.
- you have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this

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 at **www.hra.nhs.uk/patientdataandresearch**
- by asking one of the research team,
- by sending an email to tay.informationgovernance@nhs.scot, or
- by ringing us on 01382 424436.

What if something goes wrong?

If you are concerned about your participation in the study you have the right to discuss your concern with a researcher involved in the study or a doctor involved in your care.
If you have a complaint about your participation first of all please talk to the researcher.

If you are not satisfied, you can make a formal complaint to a senior member of the research team or to the Complaints Officer for NHS Tayside via:

Patient Experience Team
NHS Tayside
Ninewells Hospital

Dundee DD1 9SY
Freephone: 0800 027 5507
Email: TAY.feedback@nhs.scot

If you think you have come to harm due to taking part in the study there are no automatic arrangements to get financial compensation.

Insurance
Tayside Health Board is a member of the NHS Scotland Clinical Negligence and Other Risks Insurance Scheme (CNORIS) which gives legal liability cover of NHS Tayside for this study.

Who has reviewed this study?

This study has been reviewed and approved by [insert name of REC] who are responsible for reviewing research which is conducted in humans. The Research Ethics committee does not have any objections to this study going ahead.

Contact details for further information.

Dr Mark Spears, Department of Respiratory Medicine, Perth Royal Infirmary, Perth, PH1 1NX
Tel: 01738 473384. Email: mark.spears@nhs.scot

Thank you for taking time to read this information and for considering taking part in this study.