MRI assessment of lung ventilation around radiotherapy treatment for lung cancer

Participant Information Sheet

Version 1.1 – 18th October 2023

We invite you to take part in a research study, which we hope will benefit people with lung cancer in the future. Before you decide to do this, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information fully. Talk to others, including family and friends or your GP if you wish. Ask us if there is anything that is not clear or if you would like further information. Take time to decide whether or not you wish to take part.

What is the purpose of this study?

We are a group of researchers examining the feasibility of measuring lung function using Magnetic Resonance Imaging (MRI scanning). We are doing this to develop new ways of planning radiotherapy treatment in lung cancer.

Our research uses a special tracer gas that can be seen on MRI scans, and can be safely inhaled during MRI scanning. Our MRI scans give pictures of this tracer gas in the lungs and show us any regions of the lungs that are not working well (i.e. are poorly ventilated).

We are using MRI scanning in our research because it is a safe medical imaging method that can be performed without risking harm to the patient. There are other medical imaging techniques used to assess lung function, like CT scanning and gamma camera methods. However, these other methods use x-rays or radioactivity to produce images of lung function, which can harm patients. A motivation for our work is developing lung imaging techniques that don't involve radioactivity or x-rays.

In this study we are assessing if it is possible to use our MRI scan methods to detect parts of the lung that are poorly ventilated in patients with lung cancer who are planned to receive radiotherapy, and test how well our scans are able to characterise differences in function in different areas of the lung.

Why have I been approached?

We have invited patients who are having radiotherapy for treatment of a lung cancer to participate in our studies. We aim to test our ability to detect lung ventilation problems with our MRI scans.

Do I have to take part?

It is up to you to decide. We will describe what the study will involve and go through this information sheet. You can then take time to think it over and ask any further questions. If you are happy to take part, we will ask you to sign a consent form to show

that you have agreed to take part. You are free to withdraw at any time, without giving a reason.

What happens to me if I take part?

You would make one visit to our research centre in Newcastle upon Tyne. We will aim to arrange this visit after you have had your radiotherapy planning scan but before you start treatment. We can arrange transport to our research centre if needed. You will complete a screening questionnaire to make sure we can safely scan you with our MRI scanner. A clinically qualified member of the study team will review sections of your patient notes regarding lung function tests and view scans that have already been taken as part of your previous clinical care. You'll then have an MRI scan of your chest.

During the MRI scan you will lie in the scanner and we will scan your lungs. Scanning is quite noisy, so you'll wear headphones and we might talk to you through the headphones or give you instructions on a video screen. We will ask you to inhale an inert tracer gas through a tube and mouthpiece, and we will scan your lungs as you do this. The tracer gas can be detected by MRI, and allows us to capture images of gas flowing into and out of your lungs as you breathe. The tracer gas is a mixture of perfluoropropane and oxygen. Perfluoropropane is the tracer gas that we can detect with MRI, inhaling it has no known adverse effects.

We will ask you to breathe this tracer gas for up to 2-7 minutes, on several occasions during the scan session. The MRI scan session will last up to about 1h. After the MRI scan is finished your participation in the study will be complete. If you have consented to be contacted regarding further studies, we may do so to follow up how you are doing after your radiotherapy treatment. You are free to opt out of this follow up if you wish.

As we're not recruiting pregnant women to this study, we'll ask female participants to take a pregnancy test to confirm that they are eligible to participate. The pregnancy urine test device would be discarded immediately on site and no urine sample would be retained.

Visiting our research centre for the study

We can provide return taxi transport to the Newcastle Magnetic Resonance Centre, or provide free parking at the Newcastle Magnetic Resonance Centre. To thank you for the time you have spent attending for the scan we would like to offer you a £50 Amazon voucher.

What are the risks of taking part?

MRI scans use no radiation and are therefore considered to be very safe. However, MRI cannot be performed for some people who have certain types of medical devices or metal inside their bodies (such as pacemakers). Such people would not be able to participate in this study. Some people find the MR scanner a little confined, and some of the scans are noisy (but ear protection is provided). Please tell us if you have a fear of small spaces (claustrophobia).

Breathing in the tracer gas is not expected to have any side-effects. Our four previous studies of this kind in Newcastle, and studies by other researchers at other sites, have not led to any adverse effect or discomfort.

What are the possible benefits of taking part?

This study will not benefit you directly, but the information that we obtain may help us to develop new non-invasive methods to study lung function and detect differences in lung function within the lungs of patients with lung cancer requiring radiotherapy. We anticipate that this will be of benefit in the future to patients who are having radiotherapy.

Getting independent advice on the study

The research team will have provided you with this information sheet about the project, and are able to answer any questions that you have about the project. If you would like independent advice about participation in research studies, then you can contact the Patient Advice and Liaison Service (North of Tyne PALS – northoftynepals@nhct.nhs.uk - 0800 0320202).

What if there is any problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. When you take part in the study a member of our study team will guide you through the visits and the study – this person will be your primary contact in the event that you have any concerns or problems.

If you have any concerns that this person is unable to resolve, please contact another member of our team in the Oncology Haematology Research Unit, Ward 11, level 5, Freeman Hospital, Tel 0191 213 9995. Alternatively, you may contact an independent body (eg. the Newcastle upon Tyne Hospitals NHS Foundation Trust's Patient Advice and Liaison Service) to discuss a concern about your participation in the study. Contact information for these teams is shown above in the "*Getting independent advice on the study*" section.

In the event that something does go wrong and you are harmed during the research due to someone's negligence then you may have grounds for legal action, but you may have to pay your legal costs.

We have carefully reviewed all of the published literature relating to inhalation of the gas mixture used in this study and combined this with our own experience to date to determine the incidence of adverse events and serious side effects (where serious means requiring admission to hospital). To the best of our knowledge, no one has required medical intervention or admission to hospital following inhalation of this gas for an MRI study (i.e. no serious side effects). In our studies at Newcastle, we have performed such studies in over 70 patients with respiratory diseases and on over 50 healthy volunteers. No adverse effects have arisen from tracer gas inhalation. A medically qualified doctor is directly involved in the scan session. We consider the risk of experiencing a side effect relating to gas inhalation to be very low.

In the extremely unlikely event that oxygen in hospital were required, we would arrange for transfer by ambulance to the Royal Victoria Infirmary, Newcastle.

If you wish to make a formal complaint you can contact the Patient Relations Department through any of the details below:

Telephone: 0191 223 1382 or 0191 223 1454

Email: nuth.patient.relations@nhs.net
Address: Patient Relations Department
The Newcastle upon Tyne Hospitals NHS Foundation Trust
The Freeman Hospital
Newcastle upon Tyne
NE7 7DN

What happens if you see something unusual on my scans?

In this study we're asking participants to help as we develop a new type of MRI scan, and the information we will acquire is for research use rather than tailored for clinical purposes. The scans are not routinely examined by a radiologist, so they are not routinely checked for abnormalities. We would not expect to observe anything unusual on your scans beyond what is already known from your clinical care to date. Nonetheless, in the unlikely event that the scans give us cause for concern we would seek the advice of a radiologist to examine the scans, contact you to discuss this, and inform your GP.

How will we use information about you?

The Newcastle upon Tyne Hospitals NHS Foundation Trust is the sponsor for this study, which is based in the United Kingdom. We will need to use information from you and your medical records for this research project. This information will include your name, contact details, and results from some of your lung scans and lung function tests performed as part of your normal clinical care and held by the Newcastle upon Tyne Hospitals NHS Foundation Trust. 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. 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.

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. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

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

You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients, by asking a member of the research team, or by contacting the Newcastle upon Tyne Hospitals NHS Foundation Trust's Data Protection Officer (nuth.dpo@nhs.net).

Will my taking part in the study be kept confidential?

Yes. We will follow legal and ethical practice and all information about you will be kept confidential.

Your NHS medical records may be accessed by a clinically qualified member of the research team for the purpose of confirming your eligibility to take part in the study. This may include viewing clinic letters and the results of previous tests and scans. Only information that is relevant to the study will be recorded in our study files.

The research team will keep a record of your name and address in order to maintain contact with you throughout the study, but this information will not leave the local study team. All personal information will be stored securely in site files held at the research centres and on password protected computers used only by members of the study team. Personal contact details will be retained until after publication of the study results in scientific journals, which we anticipate being in the region of 1-3 years from the end of this 1-year study. This is to allow us to inform you of the outcome of our research. Personal data will be deleted after this time.

We may share anonymised data generated from the study with national and international academic colleagues, or industry collaborators, for the purpose of ongoing research and development of improved MRI data acquisition methods, and for dissemination of study findings. Any scan data or information leaving the study team will have your name and other identifying information removed. We use linked anonymised data. Scan data will be retained on secure networked data archives for a period of 5 years, restricted to members of the study team with authorised login credentials.

Your details will be available to people authorised to work on the study but may also need to be made available to people authorised by Newcastle upon Tyne Hospitals NHS Foundation Trust, which is the Sponsor organisation responsible for ensuring that the study is carried out correctly. By signing the consent form you agree to this access for the current study and any further research that may be conducted in relation to it.

Will you inform my GP that I'm taking part in this study?

We will ask you if you consent to us informing your GP that you are taking part in this research study. If you agree to this we will send them a letter with brief details of the study and inform them of your participation.

What if relevant new information becomes available?

If other new lung imaging tests become available whilst this study is in progress, we will inform you and discuss with you whether or not to continue. If relevant new information becomes available about the tracer gas, it will be reviewed by the sponsor of the study. We will inform you of any relevant new information and discuss with you whether or not to continue.

What will happen if I don't want to carry on with the study?

You may withdraw from the study at any time without giving a reason. If we have already obtained some MRI scans and associated data, we would like to keep and analyse these.

If you were to lose capacity to consent to participate before completing the study, we would withdraw you from the study and no further research procedures would be carried out. If we have already obtained some MRI scans and associated data, we would like to keep and analyse these.

What will happen to the results of the research study?

We will send a summary of the results to all participants at the end of the study. We will present the results at national and international meetings of health care professionals and researchers interested in lung ventilation, transplantation, respiratory medicine, and MRI scanning. We will also publish the results in scientific journals. You will not be identified in any of these reports.

Who is paying for this research study?

This study is funded by Newcastle University.

Who has reviewed the study?

The study has been reviewed by an independent group called a Research Ethics Committee, to ensure that your safety, rights, wellbeing, and dignity are protected.

Further information

If you would like further information about this project, please contact: Prof Pete Thelwall, Newcastle Magnetic Resonance Centre Campus for Ageing and Vitality Newcastle University, Newcastle upon Tyne, NE4 5PL, Telephone: 0191 208 1250 or Dr Rachel Pearson, Consultant Clinical Oncologist, Northern Centre for Cancer Care, Newcastle upon tyne, NE7 7DN, Telephone: 0191 213 9995