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MRI to optimise lung cancer radiotherapy

Submission date
07/12/2023

Recruitment status
No longer recruiting

Registration date
18/12/2023

Overall study status
Completed

Last Edited
09/01/2024

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Radiotherapy treatment of lung cancer aims to destroy tumour and prevent recurrence, whilst limiting radiation exposure to non-tumour regions. Many lung cancer patients have other lung diseases that result in heterogeneous function, and lung function can worsen in some people after radiotherapy as the treatment damages the few remaining lung regions with good function. The study team have developed 3D MRI scan measurements of lung function. This study aims to test their ability to report on lung functional heterogeneity in lung cancer patients and to test the ability to use this functional information to produce better radiotherapy treatment strategies that limit radiation impact on post-treatment lung function.

Who can participate?
Adults over 18 years old, with non-small cell lung cancer and planned to receive radical OR high dose palliative radiotherapy (+/- adjuvant chemotherapy or surgery).

What does the study involve?
The study team are a group of researchers examining the feasibility of measuring lung function using Magnetic Resonance Imaging (MRI scanning) to develop new ways of planning radiotherapy treatment for lung cancer. The research uses a special tracer gas that can be seen on MRI scans and can be safely inhaled during MRI scanning. The MRI scans give pictures of this tracer gas in the lungs and show any regions of the lungs that are not working well (i.e. are poorly ventilated). MRI scanning is used 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. The motivation for this work is to develop lung imaging techniques that do not involve radioactivity or X-rays. In this study, the team 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 planning to receive radiotherapy and test how well our scans can characterise differences in function in different areas of the lung.

What are the possible benefits and risks of participating?
This study will not benefit patients directly, but the information that is obtained may help in the

development of new non-invasive methods to study lung function and detect differences in lung function within the lungs of patients with lung cancer requiring radiotherapy. It is anticipated that this will be of benefit in the future to patients who are having radiotherapy.

Where is the study run from?
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2023 to September 2024

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Nuth.ProjectManagement@nhs.net

Contact information

Type(s)
Scientific, Principal investigator

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Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
330496

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 58734, MR/X50290X/1, IRAS 330496

Study information

Scientific Title
Using lung ventilation imaging to optimise lung cancer radiotherapy plans

Study objectives
The purpose of this pilot study is to provide initial data on regional differences in lung ventilation properties in patients receiving radiotherapy for lung cancer treatment and to compare this data to radiotherapy planning CT scans. The study is not statistically powered, no formal hypothesis testing is performed, and we have no prior data in these patient groups to inform power calculations. It is anticipated that study findings will inform power calculations in the design of downstream studies using our novel MRI methods in radiotherapy planning for patients with lung cancer.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/11/2023, London – City & East Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 1048171, (0)207 1048134, (0)207 104 8124; cityandeast.rec@hra.nhs.uk), ref: 23/PR/1087

Study design
Interventional non-randomized

Primary study design
Interventional

Study type(s)
Diagnostic, Treatment

Health condition(s) or problem(s) studied
Lung cancer

Interventions

Patients who meet the study inclusion criteria who attend outpatient cancer care clinics at Newcastle upon Tyne Hospitals NHS Foundation Trust will be identified by members of the study team. They will then be approached in person or contacted by phone, letter or email by a member of the study team to determine whether they wish to participate. They will be provided with the Participant Information Sheet and will be asked questions relating to medical history and medications by a medically qualified member of the study team. This will be performed specifically to determine that inclusion criteria are met and to screen for exclusion criteria. Participants will be invited to attend a study visit on a day convenient to them at the Newcastle Magnetic Resonance Centre.
Written informed consent will be obtained by a member of the study team after the potential participant has been allowed to read the PIS and at least 24 hours to consider participation in the study.
They will be invited to discuss any aspect of the study with the study team before giving consent. Persons who are unable to give informed consent for themselves will not be recruited to the study. Participants will be contacted by telephone to ensure they are well on the morning of or the day before the scan. Informed consent will be given on the day of the scan if it has not already been given at a prior hospital visit.
At the study visit once consent has been given/confirmed, the participant's demographic details will be recorded, a pregnancy test will be done for pre-menopausal women only, and the eligibility assessment will be confirmed.
An MRI safety questionnaire will be completed, and participants will change into MRI-compatible clothing if necessary. They will then have a single MRI scan session of the lungs, comprising three to five scans each lasting for approximately 2-7 minutes. For these, the participant will lie on the MRI scanner bed and a sensor (called an “RF coil”) will be positioned around their chest. During the scan session, each participant will be asked to inhale the tracer gas mixture (21% oxygen, 79% perfluoropropane) for approximately 2-3 minutes, followed by no less than 5 minutes of breathing room air.
After the MRI scan session is finished, participation in the study will be complete.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The percentage of ventilated lung volume (%VV) measured using fluorine MRI study data to characterise the extent of lung ventilation defects in the lungs of lung cancer patients before radiotherapy (single scan, baseline) at one time point

Key secondary outcome(s))
Regional tracer gas wash-in and wash-out rates measured using the fluorine MRI scan, and clinical lung function measured using spirometry at baseline

Completion date
30/08/2024

Eligibility

Key inclusion criteria
1. Aged 18 and over
2. Able to provide written informed consent to participate in the study
3. English speakers
4. Body weight within minimum and maximum scanner requirements of 50-100 kg

5. Diagnosed with non-small cell lung cancer by the clinical team
6. Planned to receive radical OR high dose palliative radiotherapy (+/- adjuvant chemotherapy or surgery)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients below the age of 18 years
2. Patients who are not able or decline to give informed consent to participate in the study
3. Non-English speakers
4. Body habitus incompatible with positioning within the MRI scanner sensor used for 19F-MRI (approximately equivalent to a body circumference > 120cm at chest height, and body mass index > 35 kg/m^2)
5. Pregnant or breastfeeding
6. MRI contraindications: incompatible implanted medical device (e.g. cardiac pacemaker), or metallic implants incompatible with MRI
7. Claustrophobia incompatible with MRI

Date of first enrolment
01/12/2023

Date of final enrolment
14/06/2024

Locations

Countries of recruitment
United Kingdom

Study participating centre
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The anonymised study imaging datasets and associated anonymised patient data generated during and/or analysed during the current study will be available upon request from Prof Pete Thelwall (pete.thelwall@newcastle.ac.uk) and Dr Rachel Pearson (rachel.pearson1@nhs.net) once study publication outputs are complete. Requests for anonymised study image data and associated anonymised patient data will be reviewed by the study senior team for no more than 5 years after the completion of publication outputs and data will be shared for academic research. Consent for the sharing of anonymised data is obtained from study participants.

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1	18/10/2023	18/12/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes