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Aerosol clearance in patients with and without long COVID

Submission date
08/04/2022

Recruitment status
No longer recruiting

Registration date
01/06/2022

Overall study status
Completed

Last Edited
11/07/2022

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
The goal of this research is to help determine the cause of breathlessness in people who are suffering from long COVID (ongoing symptoms more than 4 weeks since COVID-19 infection). By taking an extra measurement when performing nuclear medicine lung scans it is possible to determine how a part of the lungs called the alveolar epithelial membrane is working. It is known that this membrane can be affected by lung disease and smoking. The main aim of this study is to find out if this membrane is also affected by COVID-19. The study can do this by asking participants extra questions and taking extra pictures.

Who can participate?
Patients aged 18 years and over who have been referred to the Department of Nuclear Medicine, Ninewells Hospital, Dundee for a lung scan as part of their standard of care

What does the study involve?
A radiographer or clinical technologist will discuss the study with potential participants. Staff will ensure any questions are answered. Potential participants will have at least 1 hour to consider taking part in the study. If they decide to take part, staff will ask them to sign a consent form to give their permission after they understand all of the information. If they agree to take part in this study staff will ask them to complete a brief questionnaire before their lung scan. The questionnaire will ask about their smoking habits and the smoking habits of the people they live with. It will also ask about any heart or lung problems they may have had. Only study participants are asked to complete this questionnaire. In the first part of a nuclear medicine lung scan staff ask patients to breathe in an aerosol that contains a small amount of radioactivity. Staff then take pictures of this radioactivity while patients are lying down using a gamma camera. The radiation dose from this procedure is equivalent to around 1 month's natural background radiation. This is the standard procedure for lung scans and all patients will undergo this whether they choose to take part in this study or not. This study involves taking extra pictures which will take an additional 10 minutes. Participants will be in the same lying down position. There is no additional radiation dose from the extra pictures.

What are the possible benefits and risks of participating?
Information learned from the study may help other people in the future. Nuclear medicine lung

scans are part of a participant's routine care. If they take part in this study they will not breathe in any additional radioactivity. This procedure uses ionising radiation to form images of their body and provide their doctor with other clinical information. Ionising radiation may cause cancer many years or decades after the exposure. The chances of this happening to them are the same whether they take part in this study or not. The exam will take 10 minutes longer than if they did not take part in this study.

Where is the study run from?
Ninewells Hospital (UK)

When is the study starting and how long is it expected to run for?
February 2022 to December 2023

Who is funding the study?
NHS Tayside (UK)

Who is the main contact?
Mr Thomas J Biggans
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
313254

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
3-013-22, IRAS 313254

Study information

Scientific Title
A feasibility study to assess alveolar epithelial permeability in smoking and non-smoking control groups and patients suffering ongoing symptoms more than 4 weeks since COVID-19 infection (long COVID) using pulmonary clearance of [99mTc]DTPA aerosol measured by lung scintigraphy

Study objectives
The clearance rate of [99mTc]DTPA aerosol from the lungs in patients suffering from long COVID is higher than in control groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/05/2022, North of Scotland Research Ethics Committee (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE; +44 (0)1224 558458; gram.nosres@nhs.scot), ref: 22/NS/0061

Study design
Single-centre 1-year observational case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Long COVID

Interventions
Current intervention as of 11/07/2022:
Potential participants will be identified from the referral information on the radiology information system (RIS). No other method will be used to identify potential participants.

The majority of these exams are considered urgent and often take place within 24 hours of referral. The corresponding recruitment window is therefore short. Potential participants will be given a participant information sheet at the beginning of their appointment. The consent process will consist of discussion between the potential participant and a member of the nuclear medicine technical staff with an opportunity to ask questions. The potential participant will be given at least 1 hour to consider their participation. Informed consent will be recorded in writing using the informed consent form.

Trained nuclear medicine technical staff will then administer the study questionnaire. The questionnaire collects data on the smoking habits of the participant and those they live with. It also asks participants about their cardiac and pulmonary clinical history.

In line with the local standard clinical protocol, participants will then be positioned on the scanning bed of a gamma camera and then asked to inhale [99mTc]DTPA aerosol. The gamma camera will be used to acquire six images from different angles.

In addition to the local standard clinical protocol, a series of 20 more images will be acquired after the initial set. This series will consist of 10 anterior and posterior pairs at a rate of 1 pair per minute. Nothing further is expected of the participant after the second set of images. They will complete the second part of the scan as per the clinical protocol. This part is not included in the study.

Regions of interest (ROIs) will be drawn around the lungs on each image and the number of counts within each ROI recorded. This will be recorded along with the time the image was taken. Geometric mean counts will be plotted on a graph against the time the images were taken. Clearance half times will be calculated using this graph. The average of the two lungs will be calculated as the representative value for each participant.

Participants will be allocated into one of four patient groups using the referral data from RIS and the questionnaire data. The four groups will be:
1. Non-smoking patients with a clinical history of long COVID
2. Smoking patients with a clinical history of long COVID
3. Non-smoking patients with no history of interstitial lung or airways disease
4. Smoking patients with no history of interstitial lung or airways disease

The clearance rates of long COVID and the control group will be compared using the appropriate statistical test.

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Previous intervention:
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Trained nuclear medicine technical staff will then administer the study questionnaire. The questionnaire collects data on the smoking habits of the participant and those they live with. It also asks participants about their cardiac and pulmonary clinical history.

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4. Smoking patients with no history of interstitial lung or airways disease

The clearance rates of long COVID and the control group will be compared using the appropriate statistical test.

Intervention Type
Other

Primary outcome measure
The clearance half time of [99mTc]DTPA aerosol from the lungs measured by lung scintigraphy on the day of recruitment in non-smoking patients with a clinical history of long COVID

Secondary outcome measures
The clearance half time of [99mTc]DTPA aerosol from the lungs measured by lung scintigraphy on the day of recruitment in:
1. Smoking patients with a clinical history of long COVID
2. Non-smoking patients with no history of interstitial lung or airways disease
3. Smoking patients with no history of interstitial lung or airways disease

Overall study start date
01/02/2022

Completion date
01/12/2023

Eligibility

Key inclusion criteria
1. Patients referred to the Department of Nuclear Medicine, Ninewells Hospital, Dundee for a lung V/Q scan as part of their standard of care
2. Participants must be 18 years old or above

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
100

Key exclusion criteria
1. Below 18 years of age
2. Pregnant
3. Lack of capacity to provide informed consent
4. Involved in current research or have recently been involved in any research prior to recruitment

Date of first enrolment
08/07/2022

Date of final enrolment
08/07/2023

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Ninewells Hospital
Ninewells Avenue
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
NHS Tayside

Sponsor details
TASC R&D Office
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Sponsor type
Hospital/treatment centre

Website
http://www.nhstayside.scot.nhs.uk/index.htm

ROR
https://ror.org/000ywep40

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
NHS Tayside

Results and Publications

Publication and dissemination plan
1. Ownership of the data arising from this study resides with the study team and their respective employers. On completion of the study, the study data will be analysed and tabulated, and a clinical study report will be prepared.
2. The clinical study report will be used for publication and presentation at scientific meetings. Investigators have the right to publish orally or in writing the results of the study.
3. Summaries of results will also be made available to investigators for dissemination within their clinical areas (where appropriate and according to their discretion).

Intention to publish date
01/12/2023

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study are not expected to be made available as participants do not provide consent for data to be shared

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No