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The use of dynamic X-rays for patients with respiratory disease

Submission date	Recruitment status	[_] Prospectively registered
26/09/2019	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/12/2023	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/02/2025	Respiratory	

Plain English summary of protocol

Background and study aims
A chest X-ray is often the first test patients with breathlessness have. It can often be normal if the patient has a disease that affects the way the lungs 'move' rather than 'look'. Information about breathing requires additional breathing tests.
The aim of this study is to investigate the use of new X-ray technology, 'Dynamic Chest Radiography' (DCR) that allows several X-rays to be taken while a patient breathes. This provides a 'film' showing the way that patients' chests move while they breathe in addition to the 'snap-shot' information that a conventional chest X-ray provides about how their lungs, heart and rib cages 'look'. DCR can therefore provide a combination of information about both the structure of the lungs and how air is moving through the airways during breathing.

Who can participate?
We are looking for three groups of patients with diseases that affect the way they breathe (patients with COPD, asthma and interstitial lung disease) attending specialist clinics. Study participants are required to have DCR in addition to the pre-arranged detailed breathing test results their doctor has requested.

What does the study involve?
The test (DCR) involves a patient standing in front of an X-ray machine for 10 seconds while taking normal and then deep breaths. The process is then repeated with the patient standing side-on to the X-ray machine. Participants will be asked to complete a visual scale after the test to see how acceptable it is to them. The information from the DCR images will be compared with the detailed breathing tests to see how well the information gained matches.

What are the possible benefits and risks of participating?
There are no specific benefits to individuals from participating in the study, however they will be contributing to the development of a new imaging investigation that we hope will improve the management of future patients.

With regards to safety, DCR uses the same technology as a conventional chest X-ray but allows many more X-rays to be taken with a slight increase in radiation dose. Taking the DCR images for this study involves a small radiation dose which is the equivalent of around 4 week's additional

background radiation exposure. This is significantly less than a CT scan, the test requested by respiratory specialists for patients with these diseases.

Where is the study run from?
Royal Liverpool and Broadgreen University Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2019 to November 2022

Who is funding the study?
Respiratory Research Group, Royal Liverpool University Hospital (UK)

Who is the main contact?
Dr Rachel Burton, Rachel.Burton3@liverpoolft.nhs.uk

Contact information

Type(s)
Scientific, Principal Investigator

Contact name
Dr Hassan Burhan

Contact details
-
Liverpool
United Kingdom
-
+44 (0)151 706 3381
Hassan.burhan@liverpoolft.nhs.uk

Type(s)
Scientific

Contact name
Dr Rachel Burton

ORCID ID
http://orcid.org/0009-0000-1849-5070

Contact details
Respiratory Research
9D Office
Royal Liverpool University Hospital
Mount Vernon Street
Liverpool
United Kingdom
L7 8YE
+44 (0)151 706 3381
Rachel.Burton3@liverpoolft.nhs.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
269685

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 369685

Study information

Scientific Title
Dynamic chest radiography in patients with asthma, COPD, COVID-19 and ILD: a pilot study

Acronym
DACI

Study objectives
1. Dynamic chest radiography (DCR) is an acceptable investigation to patients with Asthma, COPD and ILD
2. It is feasible to run a DCR study at our centre
3. There is a correlation between the values obtained from DCR and pulmonary function testing in patients with asthma, COPD and ILD

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/02/2020, West Midlands - Black Country Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8284; blackcountry.rec@hra.nhs.uk), ref: 20/WM/0032

Study design
Pilot study

Primary study design
Observational

Secondary study design
Cohort 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
Asthma, chronic obstructive pulmonary disease (COPD), interstitial lung disease (ILD) and post-COVID-19 infection

Interventions
Four groups of patients will be identified from those attending the respiratory outpatient clinic: those with asthma, COPD, ILD and post-COVID-19 infection.

Patients will be due to have full pulmonary function tests (PFTs) in order to be eligible for this study. A dynamic chest X-ray will be organised to take place within 6 months of their scheduled pulmonary function tests. Women of childbearing age will be required to have a pregnancy test prior to participation. The dynamic X-ray requires two separate images; a posterio-anterior image and a lateral view. Patients will be asked to breathe normally and then take a deeper breath over a 10-second period (following a standardised protocol) while these images are acquired. During the imaging process the time to obtain analysable imaging sequences will be recorded. A separate breath-hold protocol (participants asked to take a deep breath in and hold for 7 seconds before breathing out) was performed on a subset of the post-COVID-19 infection group.

After having the dynamic chest X-ray participants will be asked to complete a visual analogue scale asking how they found the imaging process.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Dynamic chest radiography

Primary outcome measure
Patient acceptability score as measured by a Visual analogue scale (VAS) completed by participants post dynamic chest X-ray

Secondary outcome measures
1. Number of patients recruited to the study recorded per month
2. Number of days from patient consent to performing DCR, recorded post-dynamic chest X-ray
3. Time (in minutes) required for DCR imaging process (defined as time from arrival at DCR suite to image acquisition) completed post-dynamic chest X-ray
4. Lung volume measurements (in Litres) as derived by dynamic chest radiography (Maximal Inspiratory Volume (MIV), End Expiratory Volume (EEV), Vital Capacity (MIV-EEV)) measured at the point of dynamic chest imaging
5. Lung volume measurements (total lung capacity (TLC), residual volume (RV), forced vital capacity (FVC), residual volume (RV)) in litres recorded at the point of pulmonary function testing

Overall study start date
01/03/2019

Completion date
01/11/2022

Eligibility

Key inclusion criteria
1. Undergoing PFTs in the next 6 months for clinical reasons
2. Asthma group:
2.1. A clinical history in keeping with asthma
2.2. Physiological evidence of asthma (defined as post bronchodilator reversibility, variable FEV1 over time or a previous positive bronchial challenge test)
3. COPD group:
3.1. A clinical history in keeping with COPD
3.2. Physiological evidence of COPD (FEV1/FVC ratio of <0.7)
4. ILD group:
4.1. A clinical history in keeping with ILD
4.2. HRCT findings in keeping with ILD
5. Post-COVID-19 group:
5.1. Serologically confirmed COVID-19 infection
5.2. Chest X-ray or CT findings in keeping with COVID-19
5.3. At least 12 weeks post-recovery from acute COVID-19
6. Fluent spoken English - to ensure a comprehensive understanding of the research project and their proposed involvement
7. Able to achieve positioning for a PA and lateral chest X-ray for a 30-second period

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Total final enrolment
58

Key exclusion criteria
1. Unable to provide informed consent
2. Significant other respiratory co-morbidities as judged by study doctor
3. Recent/ongoing exacerbation of airways disease or interstitial lung disease within the last 4

weeks (from the recruitment date).
4. Women of child bearing age; a positive pregnancy test or refusal of pregnancy test (a negative pregnancy test on the day of DCR is a requirement).
5. Significant research-related radiation exposure in the last 12 months prior to consent (from participation in previous studies involving radiation exposure, with a research dose constraint of 0.4 mSv).

Date of first enrolment
01/12/2020

Date of final enrolment
01/11/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Liverpool and Broadgreen University Hospital
Royal Liverpool University Hospital
Prescot street
Liverpool
United Kingdom
L7 8XP

Sponsor information

Organisation
Royal Liverpool University Hospital

Sponsor details
Prescot Street
Liverpool
England
United Kingdom
L7 8XP
+44 (0)151 7062000
rgt@rlbuht.nhs.uk

Sponsor type
Hospital/treatment centre

Website

https://www.rlbuht.nhs.uk/our-hospitals/royal-liverpool-university-hospital/

ROR
https://ror.org/01ycr6b80

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Royal Liverpool University Hospital

Results and Publications

Publication and dissemination plan
Results of the trial will be published in a peer-reviewed journal following completion

Intention to publish date
26/11/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request: Rachel Burton (Rachel.Burton3@liverpoolft.nhs.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/02/2025	20/02/2025	Yes	No