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

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

## 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 'snapshot' 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

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# Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

# Integrated Research Application System (IRAS)

269685

#### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

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

# Study type(s)

Diagnostic

# 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(s)

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

# Key secondary outcome(s))

- 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

# 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

# Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

Αll

#### 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

United Kingdom

England

# 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

#### **ROR**

https://ror.org/01ycr6b80

# Funder(s)

#### Funder type

Hospital/treatment centre

#### **Funder Name**

Royal Liverpool University Hospital

# **Results and Publications**

# 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes