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Using dynamic chest x-ray to understand the lungs of individuals with cystic fibrosis

Submission date
21/10/2019

Recruitment status
No longer recruiting

Registration date
05/12/2019

Overall study status
Completed

Last Edited
09/05/2023

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cystic fibrosis is a genetic disorder that affects many body systems, most significantly the lungs. The condition is characterised by repeated flare ups of lung infections, on a background of progressive decline in overall lung function and health status. Current strategies to assess lung function either rely on taking still images (such as CT scans) or pulmonary function testing, which involves dynamic testing of lung function (such as spirometry [a breathing test involving blowing in and out of a tube] or plethysmography [a more detailed breathing test involving breathing in and out of a tube]). In CT scans changes such as how the muscles of breathing work are lost, and the subject is exposed to a relatively large dose of radiation. Pulmonary function testing can be poorly-tolerated, and its results are dependent on how well the patient tolerates the testing, and on the interpretation of the results by the examiner. Plethysmography can estimate the volume of lungs the air can hold, but can be claustrophobic, and suffers from many of the same disadvantages as spirometry, such as tolerability. Breathing tests can also be difficult to do during exacerbations of cystic fibrosis.

Dynamic x-ray captures a series of still chest images over a short (ten second) period, which are combined as a ‘live’ image, much in the same way that a series of still frames make up a film, or how a smartphone can take a picture or a video. The photo may be of higher detail than a video, but will miss out information on anything that moves. Each individual image looks much like a standard chest x-ray, but combined, they show the lungs moving in ‘real time’. The radiation needed to gather these images is the same amount as a standard chest x-ray, and can even be reduced by cutting down the length of the ‘film’ or the number of frames in each second. Information on lung volume (how much air the lungs can hold), lung ventilation (how much air is delivered to each section of lung) and breathing muscle movement can be gained from a single dynamic radiograph. The technology has only recently been developed in practice, as it requires large amounts of computer processing power to extract relevant information from the series of images captured. Each still frame is combined into a moving picture, and a computer algorithm works out the location of various moving structures in relation to one another, as well as other variables such as how much air (ventilation) certain parts of the lung receive.

In this way, dynamic x-ray may provide a useful addition to current imaging techniques used in clinical practice. The dynamic x-ray machine installed at the Liverpool Heart and Chest Hospital

(LHCH) is the first in use in Europe, and whilst the machine is currently being used at LHCH, little research has been done on the future benefits of using this technology in cystic fibrosis patients. This study aims to validate the use of dynamic chest x-ray in this population

Who can participate?
Patients aged 17 or above diagnosed with CF and attending the adult CF unit at LHCH

What does the study involve?
The study involves three parts. In the first, data collected during patients' yearly Annual Reviews will be analysed. In the second, patients will receive a dynamic chest x-ray as well as a lateral chest x-ray (taken from the side of the chest, rather than the front), as well as detailed breathing tests called plethysmography, to compare how lung volumes calculated by dynamic x-rays compare to those calculated by plethysmography. In the third, patients coming in to hospital with a flare up of their cystic fibrosis lung disease will have a dynamic x-ray at the beginning of their stay, and again at the end, to compare differences in the movement of breathing muscles before and after treatment with physiotherapy and antibiotics. There is no follow-up as part of this study

What are the possible benefits and risks of participating?
Benefits: We hope that the results of this study will provide evidence that will improve our understanding of lung problems in CF. That understanding might one day change the care of individuals with CF.
Risks: dynamic x-rays contain x-ray radiation of the same kind in a chest x-ray. This radiation dose is slightly more than that of a standard chest x-ray. As with any x-ray exposure, there is a small risk of cancer being caused as a result of the radiation. We estimate that this risk is between 1 in 80,000 and 1 in 150,000 for this study

Where is the study run from?
Liverpool Heart and Chest Hospital, UK

When is the study starting and how long is it expected to run for?
November 2019 to November 2020

Who is funding the study?
Liverpool Heart and Chest Hospital, UK

Who is the main contact?
Dr Thomas FitzMaurice

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
266778

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 266778

Study information

Scientific Title
The Utility and Validity of Dynamic Chest Radiography in Cystic Fibrosis

Acronym
Dynamic-CF

Study objectives
Dynamic chest radiographs are a new method of analyzing lung disease. They look at real-time chest movements seen on x-ray and can interpret diaphragm movement, as well as lung volume. This may be of particular use in cystic fibrosis, a disease that causes progressive deterioration of lung function, and in which during exacerbations of lung disease, it may be difficult to acquire information using traditional techniques such as spirometry or plethysmography.

Hypotheses:
1. Dynamic chest radiographs provide information on diaphragmatic movement that correlates with other measures of lung function as measured by spirometry or pulmonary function studies. The lung volumes calculated by dynamic chest x-ray correlate with those provided by body plethysmography.
2. The presence of chronic infection, CFRD, or worse spirometry is associated with altered diaphragm movement seen on dynamic chest x-ray
3. There is a correlation between lung volume calculation by dynamic chest x-ray and body plethysmography
4. Dynamic chest x-ray findings are related to spirometry and clinical markers of infection during lung flare-ups of CF

Ethics approval required

Old ethics approval format

Ethics approval(s)
1. Approved 11/10/2019, The Liverpool Heart and Chest Research and Innovation (R&I) group (Liverpool Heart and Chest Hospital, Thomas Drive, Liverpool, L14 3PE, UK; Sheila.Whyte@lhch.nhs.uk), ref: R&D 1228
2. The study Local Briefing Paper, Patient Information Leaflet and Consent Forms have met approval from the local LHCH SURE group and CF patient representatives

Study design
Observational non-controlled non-randomised single-centre prospective study

Primary study design
Observational

Secondary study design
Cross sectional 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
Cystic fibrosis

Interventions
The study is divided into three parts. In the first, data collected during patients' mandated cystic fibrosis Annual Review screen will be analysed. For this part, there is no direct patient involvement other than consent for data analysis of data already collected. In the second part, a subset of patients attending the hospital for their Annual Review will be invited to, along with the dynamic chest x-ray they receive during their annual review, also have a lateral chest x-ray and full pulmonary function studies including lung volume calculation by body plethysmography. This will take less than an hour. For the third part of the study, patients admitted to hospital with a pulmonary exacerbation of their cystic fibrosis will have a dynamic chest x-ray at the beginning, and at the resolution, of their stay in hospital. This is generally around two weeks, and the study will not influence the duration of their inpatient stay. No interventions are planned as part of this study. There is no follow-up period.

This information will be gathered at the time of data collection (i.e. retrospective analysis of Annual Screen dynamic chest radiographs, which already form part of standard care at our Trust) or during collection of dynamic chest radiographs. There is no follow-up of patients required, so as soon as dynamic radiographs are taken for the patients, data analysis can be performed.

Intervention Type
Other

Primary outcome measure
1. Lung function (in the form of diaphragmatic movement) and lung volume measured by dynamic chest radiography
2. Lung function (provided by spirometry or pulmonary function studies)
3. Lung volume (provided by body plethysmography).

This information will be gathered at the time of data collection (i.e. retrospective analysis of Annual Screen dynamic chest radiographs, which already form part of standard care at our Trust) or during collection of dynamic chest radiographs. There is no follow-up of patients required, so as soon as dynamic radiographs are taken for the patients, data analysis can be performed.

Secondary outcome measures
1. Microbial colonisation measured using patient records
2. The presence of CF-related diabetes (CFRD) measured using patient records
3. Height, weight and BMI measured using patient records

Overall study start date
01/11/2019

Completion date
01/11/2020

Eligibility

Key inclusion criteria
1. Age ≥ 17 years old
2. Attending the adult CF Unit at LHCH
3. Confirmed CF diagnosis (positive sweat test in childhood and by genotyping)
4. Able to provide informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200

Total final enrolment
154

Key exclusion criteria
1. Potentially pregnant or lactating
2. Refusal or inability to provide informed consent
3. Unable or unwilling to sit or stand to perform DCR in the radiology department

4. Unable or unwilling to follow tidal breathing instructions (e.g., holding breath or taking a deep breath)
5. Unable to perform reproducible spirometry and/or full pulmonary function studies within ATS-ERS criteria
6. Any serious or active medical or psychiatric illness, which in the opinion of the investigators, would interfere with subject treatment, assessment, or compliance with the protocol
7. For those in the validation part of the study: suffering an acute exacerbation of underlying CF
8. For those in the validation part of the study: known to be MRSA positive
9. For those in the validation or exacerbation parts of the study: significant radiation exposure within the last year (for example, numerous CT scans of chest)
10. Involved, either currently or recently, in other studies involving non-routine exposure to sources of ionising radiation

Date of first enrolment
16/12/2019

Date of final enrolment
01/03/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Liverpool Heart and Chest Hospital
Thomas Drive
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Sponsor information

Organisation
Liverpool Heart and Chest Hospital

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Sponsor type
Hospital/treatment centre

Website
https://www.lhch.nhs.uk/

ROR
https://ror.org/000849h34

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Liverpool Heart and Chest Hospital

Results and Publications

Publication and dissemination plan
We aim to publish the results of this study in a respiratory and/or CF journal. We may also present abstracts and/or posters relating to the study at conference and/or local research meetings.

Intention to publish date
01/08/2021

Individual participant data (IPD) sharing plan
The anonymised datasets generated and analysed during the current study are available upon reasonable request from Dr Thomas FitzMaurice. thomas.fitzmaurice@lhch.nhs.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/03/2020	30/03/2020	Yes	No
Results article		15/03/2022	15/03/2022	Yes	No
Results article	Feasibility results	01/05/2023	09/05/2023	Yes	No