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Gastro-oesphageal reflux in patients with cystic fibrosis and its effect on lung function.

Submission date
16/06/2015

Recruitment status
No longer recruiting

Registration date
30/06/2015

Overall study status
Completed

Last Edited
12/05/2021

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Gastro-oesophageal reflux disease (GORD) is a condition where acid from the stomach leaks out of the stomach and up into the oesophagus (gullet). It is common in patients with cystic fibrosis (CF), a genetic condition where the lungs and digestive system become clogged with mucus. Although symptoms such as heartburn and acid taste in the mouth can occur, often there are no symptoms. Studies have suggested a link between a worsening lung function and the amount of GORD. A potential mechanism is by the stomach content travelling into the lungs causing inflammation and altering the usual organisms that are present. If that is the case, there may be opportunities for new drugs and/or surgical procedures. The aim of this observational study is to investigate if GORD affects the lung function.

Who can participate?
Adult patients from the Manchester Adult Cystic Fibrosis Centre outpatient clinic diagnosed with cystic fibrosis. Healthy volunteers will also participate, for comparison purposes.

What does the study involve?
It will involve looking at sputum samples (phlegm) to assess microbiology and presence of markers of reflux aspiration. These are substances that are found in the gastrointestinal tract and that, if detected in sputum, supports presence of stomach contents in the lungs. In addition factors that may influence GORD, such as antacids tablets and enteral feeding (via a tube into the stomach) will be evaluated. GORD will be measured by using special probes that assess the function of the oesophagus, pH (acidity) and presence of gastric contents within the gullet. The participants will provide measures of lung function, clinical details, blood and sputum samples as well as complete symptom questionnaires. They will have to attend two additional clinic appointments. Sputum samples will be stored in secure freezers to allow tests to be conducted in the future. Travel expenses will be paid for.

What are the possible benefits and risks of participating?
We envisage no significant risks. Participants will be provided with an accurate assessment of their gastro-oesophageal reflux, which may be used to improve their clinical care.

Where is the study run from?
University Hospitals South Manchester (UK)

When is the study starting and how long is it expected to run for?
August 2015 to August 2018.

Who is funding the study?
Manchester Adult Cystic Fibrosis Centre (UK)

Who is the main contact?
Dr Robert Lord

Contact information

Type(s)
Scientific

Contact name
Dr Robert Lord

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Contact details
University Hospital South Manchester
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United Kingdom
M23 9LT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Gastro-oesphageal reflux in patients with cystic fibrosis and its effect on lung function: an observational study

Study objectives
In patients with cystic fibrosis, gastro-oesophageal reflux (GOR) directly impacts on respiratory disease. This is a consequence of micro-aspiration of gastric contents into the airways.We

postulate that this is a consequence of increased airway inflammation, in part due to modification of the airway microbiome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee Greater Manchester South, 13/10/2015, ref: 15/NW/0655

Study design
Single-centre longitudinal observational study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Gastro-oesophageal reflux in cystic fibrosis

Interventions
Gastro-oesphophageal reflux will be measured using 24 hour combined pH and multichannel intraluminal impedence (pH-MII) in a cohort of cystic fibrosis patients recruited from the outpatient clinic. Relevant medical history and clinical data, measures of lung function upon enrollment, blood and sputum samples will be obtained. Prevalence of GORD will be compared to severity of lung disease. The sputum samples will be analysed for both culture and non-culture dependent microbiology as well as for presence of biomarkers of extra-oesphageal GORD. We intend to enroll healthy volunteers for induced sputum to allow comparision of microbiology and biomarkers of estra-oesopahageal GORD.

Intervention Type
Other

Primary outcome measure
Determine the characteristics of GOR and its correlation to the severity of respiratory disease in patients with cystic fibrosis.
Collected at either the first or second visit. Evaluation of the notes will provide any additional data.

Secondary outcome measures

1. Evaluate the relationship between GOR and airway microbiology
2. Evaluate the correlation between proximal GOR and sputum markers of extra-oesophageal reflux
3. Evaluate proposed sputum microbiology and markers of aspiration in CF patients against healthy controls
4. Evaluate the impact on GOR characteristics of those receiving Ivacaftor, PPI or enteral feeding
5. Evaluate the impact on GOR characteristics of patients characteristics including genotype, weight and sex

Collected at either the first or second visit. Evaluation of the notes will provide any additional data.

Overall study start date
01/08/2015

Completion date
01/08/2018

Eligibility

Key inclusion criteria
1. Confirmed diagnosis of cystic fibrosis
2. Aged over 18
3. Provision of signed, written and dated informed consent, prior to any study specific procedures

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Total final enrolment
41

Key exclusion criteria
1. An acute exacerbation within two weeks of completing oral or intravenous antibiotics
2. Pregnant
3. Post-lung transplant
4. Fundoplication
5. Known infection with burkholderia cepacia complex organisms

Date of first enrolment
01/09/2015

Date of final enrolment
01/06/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals South Manchester
Southmoor Road
Manchester
United Kingdom
M21 9AX

Sponsor information

Organisation
University Hospital South Manchester

Sponsor details
Southmoor Road
Manchester
England
United Kingdom
M23 9LT

Sponsor type
Hospital/treatment centre

Website
www.uhsm.nhs.uk

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Manchester Adult Cystic Fibrosis Centre

Results and Publications

Publication and dissemination plan
We will report the findings through conferences and journals. They will also be published in a PhD thesis.

Intention to publish date
01/11/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	respiratory tract microbiome results presented at the British Thoracic Society meeting	01/12/2019	12/05/2021	Yes	No
Thesis results			12/05/2021	No	No
HRA research summary			28/06/2023	No	No