

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

<b>Submission date</b> 16/06/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/06/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/05/2021	<b>Condition category</b> Digestive System	<input type="checkbox"/> 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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<http://orcid.org/0000-0001-9008-2502>

**Contact details**  
University Hospital South Manchester  
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M23 9LT

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## Study information

**Scientific Title**  
Gastro-oesophageal 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-oesophageal reflux will be measured using 24 hour combined pH and multichannel intraluminal impedance (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-oesophageal GORD. We intend to enroll healthy volunteers for induced sputum to allow comparison of microbiology and biomarkers of extra-oesophageal 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](http://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?
<a href="#">Results article</a>	respiratory tract microbiome results presented at the British Thoracic Society meeting	01/12/2019	12/05/2021	Yes	No
<a href="#">Thesis results</a>			12/05/2021	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No