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Clinical consequences of Aspergillus disease in cystic fibrosis

Submission date	Recruitment status	[ ] Prospectively registered
21/11/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/03/2018	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/03/2018	Respiratory	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Cystic fibrosis (CF) is a genetic disease which affects the whole body, but respiratory/lung disease is the most prominent problem. Patients with CF are colonised by different bacteria and fungi which can cause lung disease of varying severity, and one of these bugs is the fungus Aspergillus. Aspergillus is a fungus that is found in the environment, and while people with normal lungs and immune system are not affected by the fungus, CF patient's lungs are particularly vulnerable to infection. There are four potential types of Aspergillus disease in CF which have been recently described in a previous study and the health consequences of these types of disease are not well known in comparison to each other. The aim of this study is to look back at the patients involved in the original study that proposed the four types of Aspergillus disease and investigate the decline in health and survival outcomes for each type. Patients may change disease type over time, therefore patients from the previous study are re-tested and re-diagnosed as an Aspergillus disease type to investigate this. As Aspergillus is found in the environment the levels of Aspergillus found in the air both in the CF unit and in patient's homes are measured using environmental sampling to understand more about the risks of acquiring Aspergillus lung disease, and the effects of ventilation in potentially reducing environmental levels.

Who can participate?
Cystic fibrosis patients aged over 18 who were involved in the previous study to classify Aspergillus disease are approached to be involved in this study

What does the study involve?
Participants have a blood sample and a sputum sample taken to re-test for Aspergillus disease type. These tests are done as part of a CF patient's normal care and do not require an extra trip to the hospital. Patients are also given the option to have their home air tested for the presence of Aspergillus, and this is done by the doctor at a home visit of less than 30 minutes.

What are the possible benefits and risks of participating?
The benefit of taking part in this study is to help increase knowledge of Aspergillus disease in CF. No risks are foreseen.

Where is the study run from?
The Manchester Adult Cystic Fibrosis Centre in Wythenshawe Hospital in Manchester (UK)

When is the study starting and how long is it expected to run for?
September 2016 to September 2018

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

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number
232722

ClinicalTrials.gov number

Secondary identifying numbers
IRAS232722

Study information

Scientific Title
Clinical consequences of Aspergillus colonisation and disease in cystic fibrosis and the role of environment in acquisition and infection

Acronym
AspCF

Study objectives
Aspergillus disease in cystic fibrosis can be classified into four phenotypes (1. No disease, 2. Allergic bronchopulmonary aspergillosis, 3. Aspergillus sensitised, 4. Aspergillus bronchitis). The diagnostic criteria for these classifications was outlined by Baxter et al. 2013 and the same patient cohort used in this study will be followed up to 9 years to review clinical consequences of each class of disease, survival outcomes, and be prospectively re-classified to ascertain whether patient change disease class over time.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Liverpool East - submission pending

Study design
Single-centre longitudinal cohort 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Pulmonary Aspergillus disease in patients with cystic fibrosis

Interventions
Patients involved in the previous trial which classified aspergillus disease by phenotype (REC ref: 07/Q1403/70) will followed up to the current day to monitor clinical outcomes and clinical decline, in order to compare the severity of each phenotype. The surviving patients will be approached to consent to reclassification of Aspergillus disease by means of blood test for Aspergillus IgE, Aspergillus IgG, Total IgE and Galactomannan, along with a sputum sample for Aspergillus. These tests form regular follow up of these patients and will not require hospital appointments above their usual outpatient follow up. They will also be asked if they will consent to environmental air sampling of their home either by drop plates being sent to them and/or microbial air sampling. Patients can choose to consent to either or both re-classification and environmental sampling.

Intervention Type
Other

Primary outcome measure
1. Diagnosis of Aspergillus phenotype by means of blood test for Aspergillus IgE, Aspergillus IgG, Total IgE and Galactomannan, along with a sputum sample for Aspergillus, both at baseline . This is compared to previous phenotype diagnosed in study REC ref: 07/Q1403/70 to establish if change in disease class has occurred
2. Comparison of survival outcomes between class 1-4 of Aspergillus disease (present day snapshot of the patient population), and rate of clinical decline (marked by FEV1 % predicted and BMI measurements taken yearly)

Secondary outcome measures
Aspergillus/fungal exposure at a patient's residence, determined by environmental sampling at baseline. This will supplement data collected as part of air quality surveys undertaken in the cystic fibrosis unit, both in inpatient and outpatient areas

Overall study start date
30/09/2016

Completion date
30/09/2018

Eligibility

Key inclusion criteria
All patients will have taken part in study REC ref: 07/Q1403/70 between 2008-2011 (number = 129). Surviving patients who have not received a lung transplant or moved away from the unit since that time will be eligible for prospective reclassification of Aspergillus disease. All 129 patients will be followed up for retrospective data.
1. Cystic fibrosis patients > 18 years old, both male and female
2. Patients who have taken part in study REC ref: 07/Q1403/70
3. Patients eligible for reclassification of Aspergillus disease if not undergone lung transplantation or not moved away from area

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

129 patients eligible for retrospective review. 84 patients eligible for reclassification of disease and environmental home sampling. The aim is to reclassify 70 patients and do environmental sampling with up to 40 patients

Key exclusion criteria
1. Non cystic fibrosis patients
2. Patients not involved in study REC reference number 07/Q1403/70
3. Patients who have undergone lung transplantation
4. Patients who have moved away from the area during follow-up time from original study

Date of first enrolment
01/01/2018

Date of final enrolment
30/09/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wythenshawe Hospital
Manchester University NHS Foundation Trust
Southmoor Road
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Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
Wythenshawe Hospital, Manchester Univaersity NHS Foundation Trust

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Southmoor Road
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England
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Sponsor type

Hospital/treatment centre

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
There is a study protocol and patient information sheet that will be available, it is not currently online. Results will be written up as part of an MD thesis. The results of both the clinical outcomes of Aspergillus disease in CF and the potential change in classification of Aspergillus disease overtime, as well as the Aspergillus environmental sampling in hospital and patient homes are planned to be submitted for publication at the end of 2018. The results of the study will also be shared with the participating patients. Interim data and results will be submitted to international conferences for both poster and presentations.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Andrew Jones.

IPD sharing plan summary
Available on request