

# Identifying the Causes and Risk Factors of Pulmonary Exacerbations in Cystic Fibrosis

NCT06940531

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**Status** RECRUITING  
**Sponsor** Alexander Horsley  
**Enrollment** 300 participants

## Key Eligibility Criteria

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### Inclusion (24)

- For Adult Participants
  - Confirmed diagnosis of cystic fibrosis (CF), defined as presence of two pathogenic CF-causing CFTR mutations AND clinical features consistent with a diagnosis of CF, OR presence of at least one pathogenic CF-causing CFTR mutation AND sweat chloride (before use of CFTR modulators)  $>60\text{mmol/L}$  AND clinical features consistent with a diagnosis of CF.
  - Age  $\geq 16$  years and receiving care from a UK Adult Cystic Fibrosis Centre for main study. 5-16yrs for Paediatric pilot study (see below).
  - Have had at least 1 previous exacerbation of CF lung disease, treated with oral or intravenous antibiotics, in the previous 12 months.
  - Able to understand the patient information sheet, willing to consent to study protocol and to returning home samples
- ... and 19 more (see full listing online)

### Exclusion (11)

- Unable to produce sputum, spontaneous or induced, at visit 1. If subject is normally able to produce sputum and still wishes to take part, visit 1 can be repeated on up to two additional occasions if this is needed to obtain sputum sample.
  - For the first visit, participants should be clinically stable at the time of the visit. This is defined as no acute change in their baseline symptoms or presence of new viral symptoms. They should not be on additional antibiotics or anti-viral therapies for any reason (above their usual medications), and should have completed any such additional therapies at least 4 weeks prior to visit 1.
  - Subjects with infection with Mycobacteria tuberculosis
  - Subjects with active ABPA, defined as receiving treatment for ABPA currently or within the last 12 months, or those considered at risk of requiring treatment for ABPA in the next 12 months.
  - Subjects receiving long term oral steroids at an equivalent dose of 10mg or more per day of prednisolone.
- ... and 6 more (see full listing online)

## Locations (18 total)

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Manchester Adult Cystic Fibrosis Centre, Manchester, Manchester, United Kingdom  
Birmingham Heartlands Hospital, Birmingham, United Kingdom  
Blackpool Teaching Hospitals, Blackpool, United Kingdom  
... and 15 more locations

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<https://clinicaltrials.gov/study/NCT06940531>

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