

# The effect on blood and sputum measures of a new drug used to treat cystic fibrosis patients

<b>Submission date</b> 18/02/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 02/03/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/04/2024	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Cystic fibrosis patients have donated sputum and blood samples to be stored in the ManARTS biobank, which is a repository of detailed clinical information and of biological samples. These samples were taken before and after commencing a new highly effective medication called Kaftrio. We will examine these samples for changes in the protein make-up related to starting this medication. This will give us a better understanding of how Kaftrio works and if any proteins might have potential as a new test to improve treatment.

Cystic fibrosis is an inherited condition that causes sticky mucus to build up in the lungs and digestive system. This causes lung infections and problems with digesting food.

### Who can participate?

The study will be conducted with patients from the Manchester Adult Cystic Fibrosis Centre.

### What does the study involve?

Samples will be examined for changes in the protein make-up related to starting Kaftrio.

### What are the possible benefits and risks of participating?

The benefits of taking part mainly relate to developing new tests that might eventually improve clinical care. We anticipate no disadvantages.

### Where is the study run from?

Manchester Adult Cystic Fibrosis Centre (UK)

### When is the study starting and how long is it expected to run for?

August 2020 to June 2023

### Who is funding the study?

North West Lung Centre charity (UK)

### Who is the main contact?

Dr Robert Lord, [robert.lord@mft.nhs.uk](mailto:robert.lord@mft.nhs.uk)

# Contact information

## Type(s)

Principal investigator

## Contact name

Dr Robert Lord

## ORCID ID

<https://orcid.org/0000-0001-9008-2502>

## Contact details

Wythenshawe Hospital  
Manchester University NHS Foundation Trust  
Southmoor Road  
Manchester  
United Kingdom  
M21 9AX  
+44 1612913518  
robert.lord@mft.nhs.uk

# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

## Protocol serial number

ManARTS application M2020-100

# Study information

## Scientific Title

The changes in sputum and plasma proteome in response to CFTR therapy

## Acronym

SPRINT

## Study objectives

Cystic fibrosis has a distinct plasma and sputum proteome that relates to severity of lung disease and is modifiable by therapies.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

No approval needed, samples collected in biobank

**Study design**

Single-centre longitudinal observational study

**Primary study design**

Observational

**Study type(s)**

Diagnostic

**Health condition(s) or problem(s) studied**

Cystic fibrosis

**Interventions**

We are using sputum and blood samples provided to a research biobank by cystic fibrosis patients commencing the drug Kaftrio. All patients have provided consent. These samples will be analysed by mass spectrometry to assess large-scale changes in protein abundance (proteome) before and after therapy

**Intervention Type**

Other

**Primary outcome(s)**

Longitudinal change in sputum and plasma proteome associated with therapy (univariate and multivariate analyses). The proteome will be measured using mass spectrometry.

**Key secondary outcome(s)**

Comparison of proteome change and clinical response to therapy measured using biobank samples and patient records at a single time point

**Completion date**

01/06/2023

**Eligibility****Key inclusion criteria**

Cystic fibrosis patients commenced on the CFTR modulator Kaftrio

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Total final enrolment**

**Key exclusion criteria**

Any factor that would be expected to significantly influence the proteome in its own right, including conditions requiring immunosuppressive medication and immunodeficiency syndromes.

**Date of first enrolment**

01/09/2020

**Date of final enrolment**

01/08/2022

**Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Manchester Adult Cystic Fibrosis Centre**

Manchester University NHS Foundation Trust

Southmoor Road

Wythenshawe

Manchester

United Kingdom

M23 9LT

**Sponsor information**

**Organisation**

Manchester University NHS Foundation Trust

**ROR**

<https://ror.org/00he80998>

**Funder(s)**

**Funder type**

Charity

**Funder Name**

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository

### **IPD sharing plan summary**

Stored in publicly available repository