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

Submission date	Recruitment status	[ ] Prospectively registered
18/02/2022	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
02/03/2022	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/04/2024	Nutritional, Metabolic, Endocrine	[ ] 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

Contact information

Type(s)
Principal Investigator

Contact name
Dr Robert Lord

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not applicable (study uses existing data)

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

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

Overall study start date
01/08/2020

Completion date
01/06/2023

Eligibility

Key inclusion criteria

Cystic fibrosis patients commenced on the CFTR modulator Kaftrio

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Total final enrolment
97

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
England

United Kingdom

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

Sponsor details
Cobbett House
Oxford Road
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England
United Kingdom
M13 9WL
+44 161 2761234
research.sponsor@mft.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://mft.nhs.uk/

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Charity

Funder Name
North West Lung Centre Charity

Results and Publications

Publication and dissemination plan
Publications and relevant conferences

Intention to publish date
01/08/2024

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