

The cystic fibrosis home sputum induction trial

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
07/10/2022	No longer recruiting	<input checked="" type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
24/10/2022	Completed	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
01/11/2022	Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Early infection in children with cystic fibrosis (CF) needs to be treated in order to prevent lung disease. Sampling the lower airway for bacterial pathogens can be difficult in children with CF who are often unable to cough up secretions even if they are unwell and have a wet cough. The CF-SpIT trial showed that the sputum induction procedure is a simple effective approach to sampling lower airway secretions in children, and is as effective as bronchoscopy and bronchoalveolar lavage in children who are unwell. The sputum induction procedure involves taking a saltwater nebuliser and having chest physiotherapy. This loosens secretions which can then be coughed up. One important consideration in introducing routine sputum induction is that it is currently performed by a health professional and takes approximately 30 minutes to perform. Staff resources are therefore a limiting factor to the universal application of the sputum-induction procedure. The current trial aims to look at whether this procedure and others can be performed equally well at home by children and their parents.

Who can participate?

Children aged between 6-18 years old from the South Wales Cystic Fibrosis Network

What does the study involve?

The Cystic Fibrosis Home Sputum-induction trial (CF HomeSpIT) will compare the microbiology yield from saliva and sputum-induction performed at home by patients and their parents, with cough swab, saliva and sputum-induction performed in the clinic. This will test whether home sampling may be used as a valuable addition to standard care in children with CF. CF-HomeSpIT also looks at microbiota in these samples, helping to understand the relationship between good and bad bacteria in these samples, and which samples are best for this scientific approach.

What are the possible benefits and risks of participating?

Any additional pathogens identified from the extra tests will be used immediately in the clinical management of the patient. There are no potentially common or serious risks to participating.

Where is the study run from?

The Children's Hospital for Wales, Heath Park, Cardiff (UK)

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

June 2022 to January 2026

Who is funding the study?

1. Cystic Fibrosis Foundation (UK)
2. Cardiff and Vale University Health Board (UK)
3. Children's Hospital for Wales (UK)

Who is the main contact?

Dr Julian Forton (UK)

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Contact information

Type(s)

Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

281516

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

19/NOV/7783, CPMS 54158, IRAS 281516

Study information

Scientific Title

The cystic fibrosis home sputum induction trial - self-management for better microbiology surveillance

Acronym

CF-HomeSpIT

Study objectives

To compare pathogen yield from home sputum induction and saliva with clinic sputum induction, saliva and cough swab in children with cystic fibrosis

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 25/07/2022, Research Ethics Service Health and Care Research Wales (Public Health Wales Meeting Room, Building 1, St. David's Park, Carmarthen SA31 3HB, Wales, UK; +44 (0)2920 230457, (0)7920 565664; Wales.REC7@wales.nhs.uk), ref: 22/WA/0196

Study design

Prospective internal-control unblinded study

Primary study design

Interventional

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Cystic fibrosis

Interventions

Home sputum induction, home saliva and clinic saliva sampling for comparative microbiology analysis and scientific microbiota analysis compared to clinic gold standard cough swab and sputum induction. There was no follow-up activity but all microbiology results will be used in the immediate clinical management of patients.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Pathogen detection rate of matched home sputum induction and home saliva versus Gold standard clinic cough swab measured using microbiology analysis as per CF Trust Microbiology Guidelines at a single time point

Key secondary outcome(s)

Pathogen detection rate of home sputum induction and home saliva versus clinic sputum induction and saliva samples measured using microbiology analysis as per CF Trust Microbiology Guidelines at a single time point

Completion date

01/01/2026

Eligibility

Key inclusion criteria

1. Cystic fibrosis
2. Using hypertonic saline as part of an established physiotherapy regimen at home

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

Key exclusion criteria

Unable to expectorate spontaneously

Date of first enrolment

09/09/2022

Date of final enrolment

09/09/2025

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre

The Children's Hospital for Wales

Heath Park

Cardiff

CF14 4XW

Cardiff

United Kingdom

CF14 4XW

Sponsor information

Organisation

Cardiff and Vale University Health Board

ROR

<https://ror.org/0489f6q08>

Funder(s)

Funder type

Charity

Funder Name

Cystic Fibrosis Foundation

Alternative Name(s)

CF Foundation, CFF

Funding Body Type

Government organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United States of America

Funder Name

Cardiff and Vale University Health Board

Funder Name

Children's Hospital for Wales

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type

Details

Date created Date added Peer reviewed? Patient-facing?

<u>HRA research summary</u>		28/06/2023	No	No	
<u>Participant information sheet</u>	version 1.1	26/07/2022	10/10/2022	No	Yes
<u>Participant information sheet</u>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<u>Protocol file</u>	version 1.1	26/07/2022	10/10/2022	No	No
<u>Study website</u>	Study website	11/11/2025	11/11/2025	No	Yes