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The cystic fibrosis home sputum induction trial

Submission date
07/10/2022

Recruitment status
Recruiting

Registration date
24/10/2022

Overall study status
Ongoing

Last Edited
01/11/2022

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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)
julian.forton@wales.nhs.uk

Study website
https://www.uhwchildren.com/respiratory/home-sputum-induction/

Contact information

Type(s)
Principal Investigator

Contact name
Dr Julian Forton

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
281516

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See trial outputs table

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 measure

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

Secondary outcome measures
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

Overall study start date
01/06/2022

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

Age group
Child

Sex
Both

Target number of participants
100

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
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Sponsor information

Organisation
Cardiff and Vale University Health Board

Sponsor details
Heath Park
Cardiff
Wales
United Kingdom
CF14 4XW
+44(0)2921846126
research.governance@wales.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.cardiffandvaleuhb.wales.nhs.uk/home

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

Publication and dissemination plan
Planned publication in a high impact peer-reviewed journal

Intention to publish date
01/03/2026

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?
Participant information sheet	version 1.1	26/07/2022	10/10/2022	No	Yes
Protocol file	version 1.1	26/07/2022	10/10/2022	No	No
HRA research summary			28/06/2023	No	No