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Exacerbation Prevention in chronic obstructive pulmonary disease (COPD) - using High Flow Therapy at home to reduce hospital readmission (EPIC-HFT UK)

Submission date
30/03/2023

Recruitment status
Recruiting

Registration date
23/05/2023

Overall study status
Ongoing

Last Edited
11/06/2025

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is a common and important problem. Patients with COPD may experience exacerbations, which are deteriorations in COPD symptoms, such as breathlessness, cough and/or sputum production. Exacerbations may be severe enough to lead to requiring hospital admission. During recovery from an exacerbation, patients can experience disabling breathlessness which limits their day-to-day activities. This can occur despite the usual care with medications, including inhalers, steroids and antibiotics for COPD. There is a technique called nasal high-flow that can improve breathlessness and reduce hospital admissions and frequency of exacerbations amongst certain patients with stable COPD.

This study is being carried out to determine whether using nasal high-flow at home in patients recovering from an exacerbation of COPD, that is severe enough to need hospitalisation, can be beneficial for these participants. It is anticipated that it may reduce the risk of being readmitted to the hospital or having a repeat exacerbation in the year following hospital discharge, and improve patients' breathlessness, ability to perform physical activities and quality of life. We will compare the effects of using nasal high-flow in addition to usual care (with inhaled medications, steroids and sometimes antibiotics), to usual care alone.

The study aims to reduce the chance of participants having another exacerbation of COPD and needing to be readmitted to the hospital, following admission to the hospital. The investigators are comparing the effects of using home humidified high-flow therapy in addition to usual the normal care for COPD (which typically involves inhalers and a course of steroids and antibiotics) to usual care alone. Participants will be monitored during their hospital admission and for twelve months after they are discharged home as part of the study.

Who can participate?
Participants will be invited to participate if they have been admitted to the hospital with an exacerbation of COPD and the investigators feel that they are most likely to benefit from using this device.

What does the study involve?
This study will take place from participants' local hospital admission after they have completed the consent process and before they are discharged from the hospital and will continue for 12 months after discharge. The study team will collect data routinely taken as part of their normal care, including age, height, weight, medical history, medications list and results of vital signs (heart rate, blood pressure, breathing rate and oxygen levels), chest x-ray and blood test already taken by the medical team looking after you. We do not need to take any extra blood tests for the study but there are some optional elements that request blood tests be performed at some sites; this is optional and participants will only do it if they want to and not taking part will not impact participants taking part in the rest of the study.

What are the possible benefits and risks of participating?
Early studies have shown that high-flow therapy may benefit certain COPD patients who have not had a recent exacerbation. Based on these studies, we think it is possible that using high-flow therapy may reduce the risk of being readmitted to the hospital or having a repeat exacerbation and improve your breathlessness and quality of life. Taking part in the study will help us confirm whether this therapy is beneficial to patients with COPD who have had a recent exacerbation. However, we do not know whether this will happen, which is the main purpose of this study. All patients taking part in the study will benefit from regular visits from the research team who are experienced in supporting patients with COPD.
We do not expect any disadvantages from taking part. There are no major reported side effects of using high-flow therapy and studies have found that patients find it comfortable to use. If patients do experience any side effects from the device, they will be asked to contact their local site. All patients receive current “best practice” therapy. All the tests involve little/no discomfort, other than the time taken to perform them. The physical activity monitor can rarely cause mild and temporary irritation. The blowing and walking tests may feel uncomfortable as they require some effort but are safe. Arterial blood gas testing, which can cause mild to moderate discomfort, is an optional part of the study. This study will require time and commitment from the patients enrolled, which the research team appreciate and are very grateful for. All participants will be closely followed up by the research team who are experienced in the management of patients with COPD. We are keen that there are no risks involved in taking part. The study will be under the guidance of a Trial Steering Committee whose job is to ensure that the trial is managed well and to monitor safety.

Where is the study run from?
Guy's and St Thomas' Hospitals (UK)

When is the study starting and how long is it expected to run for?
October 2022 to March 2027

Who is funding the study?
ResMed (UK)

Who is the main contact?
gstt.epichft@nhs.net

Study website

http://www.kcl.ac.uk/research/EPiC-HFT

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil Known

IRAS number
317677

ClinicalTrials.gov number
Nil Known

Secondary identifying numbers
IRAS 317677, CPMS 55491

Study information

Scientific Title
Exacerbation prevention in COPD - effect of home high-flow therapy versus usual care on hospital readmission or death after an acute chronic obstructive pulmonary disease (COPD) exacerbation: a UK-based multicentre randomised clinical trial

Acronym
EPiC-HFT

Study objectives
The use of home High Flow Humidified Therapy will prolong time to readmission or death following an admission to hospital with an exacerbation of COPD

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/04/2023, South East Scotland Research Ethics Committee 1 (2ndFloor, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, UK; +44 (0)7814 764 241; Sandra.Wyllie@nhslothian.scot.nhs.uk), ref: 23/SS/0036

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD)

Interventions
Participants will be randomised into two parallel arms. To minimise imbalance and allow for known prognostic factors for future exacerbations, randomisation with stratification will be implemented, using the stratification factors of long-term oxygen use prior to enrolment, sex at birth, age (65 years) and BMI (=/25 kg/m²).

Participants will be randomised to the intervention or control arm. If randomised to the intervention arm participants will subsequently then be issued with an HFT device - high flow heated humidified device system. Patients randomised to the intervention will receive standard of care plus home high-flow therapy via the LUMIS-HFT device. They will be expected to use the device for approximately 8 hours per 24-hour period where possible for 12 months. The HFT will be titrated at all sites via a standardised protocol. Those in the control arm will continue to receive standard of care as per their local site, which is a best practice based on current BTS guidelines.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
LUMIS-HFT device

Primary outcome measure
12-month all-cause admission-free survival measured using patient records

Secondary outcome measures
Assessed at 30 days, 3 months, 6 months and 12 months:
CLINICAL
1. Respiratory admissions rates
2. Exacerbation frequency and severity
3. Dose-response relationship between HFT adherence and primary and secondary outcomes
4. Time to progression to long-term oxygen therapy (LTOT)
5. Time of progression to hypercapnic respiratory failure
6. Respiratory-specific mortality. Respiratory cause will be based on formal medical certificate of cause of death.
7. All-cause mortality

PATIENT-CENTRED
8. Chronic obstructive pulmonary disease assessment test (CAT) score
9. Extended MRC-Dyspnoea (eMRCD) score
10. Pittsburgh Sleep Quality Index
11. Sputum clearance visual analogue scale
12. Hospital anxiety and depression scale
13. Quality of life (EQ-5D-5L)

HEALTH ECONOMIC
14. Healthcare resource use (COPD-related primary & secondary care contact)
15. Change in respiratory medications (inc rescue packs issued)
16. Associated cost change with the above healthcare utilisation

PHYSIOLOGICAL
17. Short physical performance battery (SPPB: timed 5 sit-to-stand, 5-STS; 4m gait speed, 4mGS; standing balance score)
18. Forced expiratory volume in 1 second (FEV1)
19. Force vital capacity (FVC)
20. End expiratory Lung Volume (EELV) measured using inspiratory capacity (IC)
21. Arterial partial pressure of carbon dioxide (PaCO2) and arterial partial pressure of oxygen (PaO2) while breathing room air (selected sites)
22. Physical Activity (day, night, sleep) (selected sites)
23. Neural Respiratory Drive (NRD) measured by 2nd intercostal space parasternal electromyogram (EMG) (selected sites)
24. Expiratory Flow Limitation (EFL) measured using force oscillation technique (impedance and reactance) (selected sites)

MECHANISTIC
25. Upper and lower airway cell counts and supernatants for measures of inflammatory cytokines, including TH1, TH2, anti-inflammatory (selected sites)
26. Whole blood for measures of inflammation, including flow cytometry and cell isolation (selected sites)

Overall study start date
01/10/2022

Completion date
19/03/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 11/06/2025:

1. Severe exacerbation of COPD*
2. Age 40+ years
3. Diagnosis of COPD as defined by GOLD criteria
4. Smoking history of >10 pack years
5. Forced expiratory volume in 1 second (FEV1) <80% predicted
6. FEV1/FVC < 0.7**
*Severity defined by admission to hospital (acute admissions unit or hospital ward)
**post bronchodilator

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Previous inclusion criteria:

1. Severe exacerbation of COPD*
2. Age 40-80 years
3. Diagnosis of COPD as defined by GOLD criteria
4. Smoking history of >10 pack years
5. Forced expiratory volume in 1 second (FEV1) <80% predicted

6. FEV1/FVC < 0.7**
*Severity defined by admission to hospital (acute admissions unit or hospital ward)
**post bronchodilator

Participant type(s)
Patient

Age group
Adult

Lower age limit
40 Years

Upper age limit
120 Years

Sex
Both

Target number of participants
502

Key exclusion criteria
1. Significant obesity (BMI >35kg/m²)
2. Clinically significant obstructive sleep apnoea syndrome requiring PAP therapy (see screening procedures for more detail)
3. Major non-COPD chronic co-morbidity that may significantly contribute to risk of readmission or death within 1 year
4. Home PAP or NIV therapy

Date of first enrolment
03/07/2023

Date of final enrolment
19/03/2026

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
Guy's and St Thomas' Hospitals
Trust Offices
Guy's Hospital
Great Maze Pond
London
United Kingdom
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Sponsor information

Organisation
Guy's and St Thomas' NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.uk/Home.aspx

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Industry

Funder Name
ResMed

Alternative Name(s)
ResMed Inc., ResMed Limited, ResMed Ltd.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

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

Intention to publish date
01/02/2028

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study will be be available upon request from gstt.epichft@nhs.net

IPD sharing plan summary
Available on request