

# Does a detailed assessment for heart disease help patients who have been admitted to hospital with a flare-up of chronic obstructive pulmonary disease (COPD)?

Submission date	Recruitment status	<input checked="" type="checkbox"/> Prospectively registered
03/10/2020	No longer recruiting	<input checked="" type="checkbox"/> Protocol
Registration date	Overall study status	<input checked="" type="checkbox"/> Statistical analysis plan
29/10/2020	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
10/06/2025	Circulatory System	

## Plain English summary of protocol

### Background and study aims

Chronic obstructive pulmonary disease (COPD) is a common lung disease which can flare up, requiring admission to hospital. Patients with COPD often have heart disease, which worsens their symptoms and increase the chances of death and hospital admission. In the short period after a flare-up of COPD, patients are also at a higher risk of heart attacks and irregular heart rhythms, which cause many hospital readmissions and deaths. Unfortunately, heart disease is often not recognised or not treated adequately in patients with COPD. The aim of this study is to test whether carefully finding and treating heart disease in patients admitted to hospital with COPD exacerbation is beneficial.

### Who can participate?

Patients admitted to the Trust's hospitals with an exacerbation of COPD can participate in the study, as long as they are over 35, have a confirmed diagnosis of COPD and do not fulfil any of the exclusion criteria.

### What does the study involve?

The researchers will randomly divide participants into two equal groups. One will receive the usual care for exacerbations of COPD. The other group, called the intervention group, will receive this as well as a structured assessment for cardiovascular disease, with the treatment of any diseases identified as recommended in existing local and (inter)national guidelines. The researchers will compare the effect of adding this extra assessment and treatment on the number of days spent alive outside hospital over the subsequent year (this is the primary outcome of the study). The researchers will also measure how markers of strain on the heart change during and after COPD exacerbations in the participants that have the extra tests. Finally, they will assess how participants' quality of life evolves during the study period, as well as assessing the healthcare services they use and the medications they are prescribed.

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

For participants who are assigned to the intervention group, it is hoped that it will be possible to identify heart problems at an early stage so that the right treatment can be started. Although it is not yet known for certain whether early identification and treatment of heart problems will have a positive impact on health, the researchers believe that it will. Participants assigned to the usual care group will still receive high quality, evidence-based care and will be helped to improve the treatment and prevention of COPD exacerbations. It is hoped that this will benefit other patients with COPD in future, and it may benefit the participants directly.

### Where is the study run from?

Northumbria Healthcare NHS Foundation Trust (UK)

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

September 2020 to May 2023

### Who is funding the study?

1. Chiesi Limited (UK)
2. Northumbria Healthcare NHS Foundation Trust (UK)

### Who is the main contact?

1. Dr John Steer

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2. Dr Joe Kibbler

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## Contact information

### Type(s)

Scientific

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

277817

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

CPMS 47350, IRAS 277817

## Study information

### Scientific Title

Structured cardiac assessment and treatment following exacerbations of chronic obstructive pulmonary disease: a pilot randomised controlled trial

### Acronym

SCATECOPD

### Study objectives

A comprehensive, structured cardiovascular assessment, with treatment of problems identified, increases the time patients spend alive outside of hospital following hospital admission for a COPD exacerbation.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 23/11/2020, East of Scotland Research Ethics Service (EoSRES) (Ninewells Hospital & Medical School, Tayside Medical Science Centre (TASC), Residency Block, Level 3, George Pirie Way, Dundee, DD1 9SY; +44 (0)1382 383848; tay.eosres@nhs.scot), ref 20/ES/0112

### Study design

Single-centre pilot randomized controlled trial

**Primary study design**

Interventional

**Study type(s)**

Screening

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

Identification of cardiovascular disease (CVD) in patients admitted to hospital with COPD exacerbations.

**Interventions**

Participants will be randomized to receive usual care for COPD exacerbation, or to receive usual care plus structured assessment for cardiovascular disease. Stratified randomisation by the presence of known cardiovascular disease and PEARL score (a validated method of predicting the likelihood of readmission with COPD exacerbation) will be used.

Cardiovascular disease identified by the structured assessment will be treated according to current UK standard care in keeping with local and/or national guidance. The intervention is a detailed cardiovascular assessment: transthoracic echocardiography, cardiac biomarker assessment, 24-h cardiac monitoring, CT coronary artery calcification quantification, and assessment for hypertension. Treatment of identified cardiovascular disease will be in line with current local and/or national guidance and will be led by the usual care team.

Participants will be reviewed clinically 90 days and 12 months following hospital discharge. All will undergo a clinical assessment, spirometry, quality of life questionnaires, assessment of walking speed, and an assessment of health resource use. At 90 days, those in the intervention arm will have repeat electrocardiography, transthoracic echocardiography and cardiac biomarker measurements. Participants will also be contacted by telephone at 6 and 9 months after discharge to gather information about their medication use and interaction with healthcare services.

**Intervention Type**

Mixed

**Primary outcome(s)**

The number of days spent alive outside of a hospital environment, measured using electronic hospital records during 12 months post hospital discharge

**Key secondary outcome(s)**

1. Time to readmission or death following hospital admission for ECOPD, collected from hospital health records using Patient Administration System (PAS)
2. All-cause readmission rates at 90 days and 12 months post discharge, collected from hospital health records using Patient Administration System (PAS)
3. All-cause mortality rates at 90 days and 12 months post discharge, collected from hospital health records using Patient Administration System (PAS)
4. COPD exacerbation rates, from health records and self-report, at 90 days and 12 months
5. Rates of adverse cardiovascular events (nonfatal stroke or myocardial infarction, and cardiovascular death) at 90 days and 12 months post discharge
6. Rate of new diagnosis of cardiovascular disease at 90 days and 12 months
7. Rate of undertreated cardiovascular disease at baseline, 90 days and 12 months
8. Change in 4-m gait speed at 90 days and 12 months, compared to baseline

9. Mean change in quality of life measured by St. Georges' Respiratory Questionnaire over 12 months
10. Health costs and estimated Quality-Adjusted Life Years (QALY), measured by health records and patient-completed resource utilisation proforma, at 12 months

In the intervention arm the researchers will also report as secondary outcomes:

11. Changes in right heart function (estimated pulmonary artery systolic pressure [PASP] and tricuspid annular plane systolic excursion [TAPSE] measured by echocardiography) between baseline and 90 days
12. Relationship between changes in right heart function (estimated pulmonary artery systolic pressure [PASP] and tricuspid annular plane systolic excursion [TAPSE] measured by echocardiography) and ECOPD severity measured using DECAF score at admission and 90 days
13. Relationship between changes in right heart function (estimated pulmonary artery systolic pressure [PASP] and tricuspid annular plane systolic excursion [TAPSE] measured by echocardiography) and comorbid CVD at admission and 90 days
14. Relationship between right heart function (estimated pulmonary artery systolic pressure [PASP] and tricuspid annular plane systolic excursion [TAPSE] measured by echocardiography) and COPD severity at baseline
15. The associations between the primary outcome and right heart function (estimated pulmonary artery systolic pressure [PASP] and tricuspid annular plane systolic excursion [TAPSE] measured by echocardiography) at baseline

#### **Completion date**

31/05/2023

## **Eligibility**

#### **Key inclusion criteria**

1. Age >35 years
2. Current/former smoker & smoking burden >10 pack-years
3. Clinical diagnosis of COPD, supported by previous obstructive spirometry
4. Admission to hospital with the primary cause being an exacerbation of COPD

#### **Participant type(s)**

Patient

#### **Healthy volunteers allowed**

No

#### **Age group**

Adult

#### **Lower age limit**

35 years

#### **Sex**

All

#### **Total final enrolment**

115

## **Key exclusion criteria**

1. Reason for admission not ECOPD in view of attending clinical team
2. Unable to provide informed consent
3. Any non-COPD condition likely to limit survival to less than 12 months
4. Contraindication to non contrast CT scan
5. Pregnancy or breastfeeding

## **Date of first enrolment**

30/11/2020

## **Date of final enrolment**

02/06/2022

## **Locations**

### **Countries of recruitment**

United Kingdom

England

### **Study participating centre**

**North Tyneside General Hospital**

Northumbria Healthcare NHS Foundation Trust

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North Shields, Tyne and Wear

United Kingdom

NE29 8NH

## **Sponsor information**

### **Organisation**

Northumbria Healthcare NHS Foundation Trust

### **ROR**

<https://ror.org/01gfeyd95>

## **Funder(s)**

### **Funder type**

Industry

### **Funder Name**

Chiesi Farmaceutici

**Alternative Name(s)**

Chiesi Pharmaceuticals, CHIESI Farmaceutici S.p.A., CHIESI, CHIESI GROUP

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

Italy

**Funder Name**

Northumbria Healthcare NHS Foundation Trust

**Funder Name**

National Institute for Health Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

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

Anonymised participant-level data can be shared after the main results have been published. Applications should be made to the Trial Steering Committee who will consider all requests.

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type

Details

Date created Date added Peer reviewed? Patient-facing?

<a href="#"><u>Results article</u></a>		07/03/2025	10/06/2025	Yes	No
<a href="#"><u>HRA research summary</u></a>		28/06/2023	No		No
<a href="#"><u>Participant information sheet</u></a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#"><u>Protocol file</u></a>	version v1	01/09/2020	05/11/2020	No	No
<a href="#"><u>Statistical Analysis Plan</u></a>	version 1.0		11/04/2023	No	No