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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
03/10/2020

Recruitment status
No longer recruiting

Registration date
29/10/2020

Overall study status
Completed

Last Edited
10/06/2025

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

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 help 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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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
277817

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

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

Secondary outcome measures
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

Overall study start date
01/09/2020

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

Age group
Adult

Lower age limit
35 Years

Sex
Both

Target number of participants
120

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
England

United Kingdom

Study participating centre
North Tyneside General Hospital
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Sponsor information

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Sponsor type
Hospital/treatment centre

Website
https://www.northumbria.nhs.uk/

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

Publication and dissemination plan
The researchers plan to present preliminary results at an international conference at the end of 2022 / early 2023 with the publication of the main paper in a leading peer-reviewed journal towards the end of 2023.

Intention to publish date
01/04/2024

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?
Protocol file	version v1	01/09/2020	05/11/2020	No	No
Statistical Analysis Plan	version 1.0		11/04/2023	No	No
HRA research summary			28/06/2023	No	No
Results article		07/03/2025	10/06/2025	Yes	No