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Development of a scoring system to predict risk of death in exacerbations of chronic obstructive pulmonary disease (COPD) requiring assisted ventilation.

Submission date
23/06/2015

Recruitment status
No longer recruiting

Registration date
07/08/2015

Overall study status
Completed

Last Edited
02/11/2022

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
COPD is a common chronic lung disease. Acute exacerbations (AECOPD) are often triggered by infection and are the second commonest reason for hospital admission in the UK. Severe exacerbations resulting in respiratory failure are associated with high mortality (death), which is reduced by 2-3 times by the use of non-invasive ventilation (NIV). Unfortunately the national COPD audit showed that of 26% of patients who met the criteria for ventilation, only 12% received it. In part, this reflects difficulty in accurately predicting outcome following NIV and widespread prognostic pessimism. Decisions about suitability for ventilation should be informed by reliable estimates of the patients' chance of surviving the acute event and subsequent outcomes. Clinicians are unduly pessimistic as shown in a recent study (CAOS); actual six-month survival was four-fold better than predicted in some patients. Most survivors would choose ventilation again. Prognostic tools outperform clinicians' estimates in most settings. The trialists will assess outcomes following AECOPD requiring ventilation and develop simple prognostic tools assessing in-hospital mortality.

Who can participate?
The study is retrospective (i.e. looking at events that have already occurred). It will include all those admitted consecutively to our trust with AECOPD requiring assisted ventilation from December 2008 onwards until at least 425 patients have been identified and included.

What does the study involve?
The patients included in the study are not exposed to any test or treatment only collection of data from case records. Any analysis or publication of data is anonymised . As such individual patient consent is not being sought for inclusion in the study. This approach has been approved by both patient focus group and a research ethics committee.

What are the possible benefits and risks of participating?
It is hoped that the successful development of a predictive tool will lead to better decision in a

life-threatening situation. Nihilism will be challenged and more patients will consequently receive non-invasive ventilation. There are no perceived risks of participation.

Where is the study run from?
North Tyneside General Hospital (UK)

When is the study starting and how long is it expected to run for?
May 2014 to May 2016.

Who is funding the study?
Northumbria Healthcare NHS Foundation Trust (UK)

Who is the main contact?
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Contact information

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol ref v4.1

Study information

Scientific Title
Derivation of a novel scoring system to predict inpatient mortality in exacerbations of chronic obstructive pulmonary disease requiring assisted ventilation.

Study objectives
Clinicians' estimate of survival and prognosis is poor and is consistently outperformed by predictive tools. In acute exacerbations of COPD (AECOPD) requiring assisted ventilation the CAOS study highlighted pronostic nihilism. The national COPD audit showed that 26% of patients developed respiratory acidaemia but only 12% were ventilated. No predictive tool is routinely used in clinical practice in this group. The use of non-invasive ventilation is widespread and often initiated by the non specialist. Developing a predictive tool to augment decision making will reduce nihilism and increase use of a treatment shown to save lives, allow better prognostic information to be shared with a patient leading to shared decision making and in a small number of patients highlight the importance of palliative care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Liverpool Central 29/5/2015, ref: 15/NW/0389

Study design
Observational single-centre study

Primary study design
Observational

Secondary study design

Study setting(s)
Hospital

Study type(s)
Other

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

Consecutive patients with acute exacerbation of chronic obstructive pulmonary disease (AECOPD) requiring assisted ventilation will be identified. Indices including; socio-demographic data, biochemical, clinical data and functional status will be collected. Variables related to mortality on univariate analysis will be identified. Eligible variables will be entered into backward stepwise logistic regression, with in-hospital mortality as the dependant variable. To ensure that the final model can be easily applied at the bedside, the final number of variables will be reduced to the minimum required to maintain prediction of in-hospital mortality. Performance will be assessed by AUROC curve. Mortality and readmission rates will be compared in patients with and without predefined characteristics, namely: Late failure of NIV, persistent hypercapnia, long term oxygen, long term ventilation.

Intervention Type
Mixed

Primary outcome measure
Prediction of in-hospital mortality within the derivation cohort, assessed by the area under the receiver operating characteristic (AUROC) curve for tools developed using:
1. Indices available on admission
2. All indices up to and including the time of deterioration

Secondary outcome measures
1. Comparison of the AUROC curves for both novel tools
2. Comparison of the AUROC curves for both novel tools to CAPS and APACHE II
3. 30 day, 90 day, 180 day and 1 year mortality
4. 30 and 90 day readmission rates
5. Comparison of outcomes in patients with, and without pre-defined characteristics:
5.1. Late failure of NIV (recurrent respiratory acidaemia, despite on-going ventilatory support)
5.2. Persistent hypercapnia
5.3. Long-term oxygen therapy
5.4. Long-term ventilation on discharge

Overall study start date
01/05/2014

Completion date
01/05/2016

Eligibility

Key inclusion criteria
1. Aged over 35 years
2. Smoking history greater than or equal to 10 pack years
3. Obstructive spirometry (FEV1/FVC < 0.7)
4. AECOPD primary diagnosis
5. Respiratory acidosis treated with NIV or IPPV (arterial blood gas pH <7.35, pCO_2 > 6.0)

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
425

Total final enrolment
489

Key exclusion criteria
1. Previous inclusion in the study
2. Other illness likely to limit survival to less than 1 year

Date of first enrolment
01/07/2015

Date of final enrolment
01/02/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North Tyneside General Hospital
Rake Lane
North Shields
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NE29 8NH

Study participating centre
Wansbeck General Hopsital
Woodhorn Lane
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Sponsor information

Organisation
Northumbria Healthcare NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01gfeyd95

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Research and Development Department, Northumbria Healthcare NHS Foundation Trust

Results and Publications

Publication and dissemination plan
This work is linked to a validation project. Publications will be prepared and presented upon completion of the validation study. Results of both studies will be presented together.

Intention to publish date
01/08/2019

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/08/2021	02/11/2022	Yes	No

HRA research summary	28/06/2023	No	No