

# Survival, quality of life and health resource use following hospitalisation for chronic obstructive pulmonary disease (COPD) exacerbations

<b>Submission date</b> 10/08/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/05/2013	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Stephen Bourke

**Contact details**  
North Tyneside General Hospital  
Rake Lane  
North Shields  
Newcastle-upon-Tyne  
United Kingdom  
NE29 8NH

## Additional identifiers

### Study information

**Scientific Title**  
Survival, quality of life and health resource use following hospitalisation for chronic obstructive pulmonary disease (COPD) exacerbations: a longitudinal, single-centre, observational study

**Study objectives**

Acute exacerbations of chronic obstructive pulmonary disease (COPD) account for 10% of hospital admissions and 90-day mortality stands at 15.3%. Mortality increases with frequency of exacerbations, particularly when severe. In patients with severe exacerbations complicated by acute respiratory failure, non-invasive ventilation (NIV) improves survival but is still associated with a one-year mortality of approximately 50%. In these patients with a severe exacerbation, little is known regarding the use of NIV and quality of life and hence there is a lack of clarity regarding whether patients with the most severe exacerbations should be considered for NIV. We therefore intend to assess mortality, quality of life, exacerbation frequency and hospital admissions among survivors of exacerbations of COPD requiring NIV (n = 150) and exacerbations of COPD not requiring NIV (n = 150).

Patients with severe COPD would benefit from input from the palliative care services in addition to optimal medical therapy. Despite evidence that patients with severe COPD have a low quality of life, high levels of disability and high levels of anxiety and depression, current input from palliative care services in this cohort is virtually non-existent. This is largely due to the difficulty in identifying which patients are unlikely to survive more than 6 months and hence should be referred to palliative care services. We therefore intend to identify univariate and independent predictors of in-hospital and six month survival in exacerbations of COPD requiring NIV (n = 150) and exacerbations of COPD not requiring NIV (n = 450).

We also intend to validate a modified Medical Research Council (MRC) Dyspnoea Scale which has previously been shown (in unpublished data) to more accurately predict markers of poor outcome when compared to the original instrument. We will compare the relations of the novel modified MRC Dyspnoea Scale and the standard MRC Dyspnoea Scale with survival, quality of life, readmission rates, length of stay and frequency of hospital admissions.

We therefore intend to recruit 600 patients admitted to Northumbria NHS Foundation Trust with an acute exacerbation of COPD and assess a variety of prognostic indices. A subset of 300 patients will undergo serial assessment of quality of life, health resource utilisation and provision of palliative care services. Provision of palliative care services will be assessed by interviewing the patient and their carers/family, contacting their GP and reviewing their medical notes.

Please note that as of 20/02/2009 this record was updated to include amended trial dates. The initial trial dates at the time of registration were:

Initial anticipated start date: 01/10/2008

Initial anticipated end date: 30/09/2010

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Added 20/02/2009: County Durham and Tees Valley 1 Research Ethics Committee approved on 28th November 2008 (ref: 08/H0905/88)

### **Primary study design**

Observational

### **Study design**

Longitudinal, single-centre, observational study

**Study type(s)**

Quality of life

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

Acute exacerbations of chronic obstructive pulmonary disease (COPD)

**Interventions**

All patients admitted who satisfy the above inclusion and exclusion criteria will be invited to participate in the study. We intend to recruit 150 patients requiring non-invasive ventilation (NIV) and 450 who do not require NIV.

A number of prognostic indices will be assessed; age, gender, body mass index (BMI), frequency of exacerbations, frequency of admissions, previous spirometry, smoking history, exercise tolerance, ability to perform ADLs, performance status, previous pulmonary rehabilitation, previous ventilation, previous NIV, a number of physiological indices, chest x-ray (CXR) report, "do not resuscitate" (DNR) order, ability to cough, treatment on discharge, spirometry on discharge, discharge destination.

Mortality data, including cause of death, will be determined in all patients by review of hospital notes and contacting the GP.

All patients requiring NIV and the first 150 patients not requiring NIV will undergo serial assessment of quality of life, oxygen saturations, BMI, spirometry and MRC Dyspnoea Score. These assessments will be performed at discharge, 6 weeks, 3 months and 3 monthly intervals for 1 year.

Total duration of follow-up: 1 year

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

1. In-hospital and 6 month survival
2. Univariate and independent predictors of in-hospital and 6 month survival

**Key secondary outcome(s)**

1. Duration quality of life maintained above baseline
2. Mean improvement in quality of life, assessed in 150 patients not requiring NIV and 150 patients requiring NIV at discharge, 6 weeks, 3 months and then 3 monthly intervals for 1 year. This will be assessed by the following: St. Georges Respiratory Questionnaire, 36-item Short Form health survey (SF-36), Hospital Anxiety and Depression Score, Nottingham Extended Activities of Daily Living Scale
3. Discharge destination
4. Frequency of exacerbations
5. Frequency of hospital admissions and length of stay
6. Provision of palliative care services

**Completion date**

30/11/2010

## Eligibility

### Key inclusion criteria

1. Both males and females, age over 40 years
2. Current or former smoker with a smoking history greater than 10 pack years
3. Diagnosis of chronic obstructive pulmonary disease, supported by spirometry
4. Infective exacerbation or pneumonia

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Sex

All

### Key exclusion criteria

1. Malignancy or other serious life-threatening co-morbidity
2. Severe cognitive impairment/dementia
3. Domiciliary ventilatory support prior to admission

### Date of first enrolment

01/12/2008

### Date of final enrolment

30/11/2010

## Locations

### Countries of recruitment

United Kingdom

England

### Study participating centre

**North Tyneside General Hospital**

Newcastle-upon-Tyne

United Kingdom

NE29 8NH

# Sponsor information

## Organisation

Northumbria Healthcare NHS Foundation Trust (UK)

## ROR

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

# Funder(s)

## Funder type

Government

## Funder Name

Northumbria Healthcare NHS Foundation Trust (UK)

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	dyspnoea and pneumonia results	01/02/2012		Yes	No
<a href="#">Results article</a>	results	01/11/2012		Yes	No