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

Submission date
10/08/2008

Recruitment status
No longer recruiting

Registration date
12/09/2008

Overall study status
Completed

Last Edited
22/05/2013

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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)

Study design
Longitudinal, single-centre, observational study

Primary study design
Observational

Secondary study design
Single-centre

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/12/2008

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

Age group
Adult

Sex
Both

Target number of participants
600

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
England

United Kingdom

Study participating centre
North Tyneside General Hospital
Newcastle-upon-Tyne
United Kingdom
NE29 8NH

Sponsor information

Organisation
Northumbria Healthcare NHS Foundation Trust (UK)

Sponsor details
Rake Lane
North Shields
Newcastle-upon-Tyne
England
United Kingdom
NE29 8NH
contact.centre@northumbria.nhs.uk

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/01gfeyd95

Funder(s)

Funder type
Government

Funder Name
Northumbria Healthcare NHS Foundation Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Results article	dyspnoea and pneumonia results	01/02/2012		Yes	No
Results article	results	01/11/2012		Yes	No