ISRCTN22921168 https://doi.org/10.1186/ISRCTN22921168

Non Invasive Ventilation in COPD: Predicting outcome in hospital and assessing quality of life over one year

Submission date
09/05/2016

Recruitment status
No longer recruiting

Registration date
04/07/2016

Overall study status
Completed

Last Edited
17/08/2022

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is the name given to a collection of diseases which affect the lungs. It is characterised by breathlessness, cough and excess mucus production and is often caused by smoking. COPD is frequently complicated by episodes of sudden worsening of respiratory symptoms, termed 'exacerbations'. Sometimes during an exacerbation waste gases rise to a dangerous level. In this setting additional breathing support may be required. This 'assisted ventilation'can be in the form of a tube placed directly into the patient's lungs or much more commonly in the form of a tight fitting facial mask. This technique is called non-invasive ventilation (NIV) and can be lifesaving. Determining which patients should receive NIV is a complex decision that requires an assessment of an individual's chances of survival should NIV be provided. However even specialist clinicians are overly pessimistic about the results of NIV treatment, which may lead to patients being inappropriately denied treatment. A simple, reliable tool to accurately identify patients likely to benefit and enhance clinical decision making has tremendous potential to further increase appropriate use of NIV. The study team has developed a score (tool) to predict the chance of successful treatment if NIV is started. For this score to be used in day to day practice it needs to be tested to ensure it works as expected. Therefore data will be collected about the health of a group of patients who experience assisted ventilation over a year. The aim of this study is to assess whether this tool is able to predict the outcome of assisted ventilation. In a second part of the study, a group of patients that have previously received assisted ventilation will be followed up over one year and data about their quality of life and the impact of COPD on their day to day activities will be collected. This data will allow clinicians to better understand what a patient experiences after ventilation. From this information particular markers of poor quality of life may be identified.

Who can participate?
Adults aged 35 and over with COPD who smoke a pack of cigarettes a day for 10 years and need treatment with a breathing machine.

What does the study involve?
In the first part of the study, information about patient's health is collected by their usual care

team over the course of one year and stored in a database. The tool is then applied to the data in order to find out if it would have accurately predicted the outcome of the patient, had the tool been applied to the patient at the time that they received ventilation. In the second part of the study, at baseline (immediately prior to discharge) and then again after three, six and twelve months, patients complete a number of questionnaires about their state of health as well as simple physical test such as their oxygen levels and weight, in order to assess their quality of life, the impact of COPD on their lives and whether they would wish to have ventilation again in the future should the need arise.

What are the possible benefits and risks of participating?
There are no direct benefits or risks to participants taking part in this study.

Where is the study run from?
1. North Tyneside General Hospital (UK)
2. Guy's Hospital, London (UK)
3. St Thomas' Hospital, London (UK)
4. Queen's Medical Centre, Nottingham (UK)
5. St James's University Hospital, Leeds (UK)
6. Queen Elizabeth Hospital, Gateshead (UK)
7. South Tyneside General Hospital, South Shields (UK)
8.Musgrove Hospital, Taunton (UK)
9. Derriford Hospital, Plymouth (UK)
10. Prince Philip Hospital, Llanelli (UK)
11. John Radcliffe Hospital, Oxford (UK)
12.Churchill Hospital, Oxford (UK)

When is the study starting and how long is it expected to run for?
May 2015 to November 2020

Who is funding the study?
1. Philips Respironics (UK)
2. Pfizer OpenAir (UK)

Who is the main contact?
1. Ms Victoria Ferguson (public)
2. Dr Tom Hartley (scientific)

Contact information

Type(s)
Public

Contact name
Ms Victoria Ferguson

Contact details
Research and Development Department
North Tyneside General Hospital
North Shields
United Kingdom
NE29 8NH

Type(s)
Scientific

Contact name
Dr Tom Hartley

Contact details
Research and Development Department
North Tyneside General Hospital
North Shields
United Kingdom
NE29 8NH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
V2.3

Study information

Scientific Title
Validation of a novel scoring system to predict inpatient mortality in exacerbations of Chronic Obstructive Pulmonary Disease requiring assisted ventilation with supplementary longitudinal assessment of quality of life and other patient-centred outcomes over one year

Acronym
NIVO

Study objectives
There are no existing tools in use routinely in clinical practice to predict outcomes following an exacerbation of chronic obstructive pulmonary disease (COPD) requiring assisted ventilation. We are developing a tool to predict in-hospital mortality (ISRCTN16977236). Among patients who survive to discharge, little is known about patient-centred outcomes including quality of life, functional status and survival; a better understanding of such outcomes would help inform appropriate future care planning, including palliative care.

The principal aims of this study are:
1. To prospectively validate the tool to predict in-hospital mortality in multiple centres
2. Among patients who survive to discharge, to identify predictors of six month mortality and perform longitudinal assessment of patient-centred outcomes including quality of life and functional status. Patients' views regarding their recent experience of assisted ventilation and willingness to undergo such treatment again will also be captured.

Ethics approval required

Old ethics approval format

Ethics approval(s)
North East - Tyne & Wear South Research Ethics Committee, 11/07/2016, ref: 16/NE/0213, IRAS project ID: 206694

Study design
Cross-sectional observation study with longitudinal follow up

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

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
Chronic obstructive pulmonary disease (COPD)

Interventions
Validation study
Each patient meeting selection criteria has a dataset collected by their usual care team. This data comprises descriptive indices, the components of our derived tool and other comparative tools, other clinical indices and mortality and readmissions to one year. Anonymised data is entered onto a centralised database. Following completion performance of the tool will be assessed by AUROC curve analysis.

Longitudinal study:
At baseline (immediately prior to discharge), 3, 6 and 12 months questionnaires and physical tests (spirometry, weight, oxygen saturation) are measured in a face to face interview either in hospital or patient's home. In addition, at baseline and 3 months future ventilation questions are asked. Every month throughout the study (i.e. months 1-12) the patient complete the following questionnaires which will be given out and collected at researcher visits: COPD assessment test (CAT), extended medical research council dyspnoea score (eMRCD), Nottingham extended activity of daily living scale (NEADL), EQ-5D-5L and hospital anxiety and depression score (HADS).

Intervention Type
Other

Primary outcome measure
Prediction of in-hospital mortality within the validation 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
In the admitted population:
1. Comparison of the AUROC curves for both novel tools
2. Comparison of the AUROC curves for both novel tools to CAPS, APACHE II and Confalonieri risk chart

Among patients surviving to discharge:
1. Mortality to 1 year by review of electronic record, contacting GP or review of patient notes
2. Readmission rates at 30, 90 and 365 days by review of electronic record, contacting GP, review of patient notes
3. Comparison of mortality and clinically significant change in quality of life in patients with, and without pre-defined characteristics:
3.1. Late failure of NIV (recurrent respiratory acidaemia, despite on-going ventilatory support; in-patient mortality will also be captured).
3.2. Persistent hypercapnia.
3.3. Long-term oxygen therapy.
3.4. Long-term ventilation on discharge.
3.5. Eosinopenia (<0.05 109/L) at discharge
4. Longitudinal changes in patient reported outcomes (CAT, eQ-5D-5L, NEADL, HADS) post discharge, quantified by calculating: mean change (relative to the minimum clinically important difference (MCID)); duration maintained above baseline and time taken to reach peak
5. Predictors of a) 6 month mortality and b) poor baseline QoL with a subsequent clinically significant deterioration (poor recovery)
6. Relation between clinically significant anxiety and depression on discharge and: survival, QoL, functional status and readmission rate
7. Examination of patient willingness to undergo ventilation again in the future by direct questioning at baseline and 3 months

Overall study start date
05/05/2015

Completion date
30/11/2020

Eligibility

Key inclusion criteria
1. Age 35 years or older
2. Smoking history greater than or equal to 10 pack years (1 pack per day for 10 years)
3. Obstructive spirometry (FEV1/FVC < 0.7)
4. Acute exacerbation of COPD (AECOPD) primary diagnosis
5. Respiratory acidosis treated with NIV or IPPV (arterial blood gas pH <7.35, pCO_2 > 6.5)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
425 (minimum)

Total final enrolment
844

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
18/10/2016

Date of final enrolment
28/02/2018

Locations

Countries of recruitment
England

United Kingdom

Wales

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

Study participating centre
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre

St Thomas' Hospital
Westminster Bridge Road
SE1 7EH
United Kingdom
LS9 7TF

Study participating centre
Queen's Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
St James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Queen Elizabeth Hospital
Queen Elizabeth Avenue
Sheriff Hill
Gateshead
United Kingdom
NE9 6SX

Study participating centre
South Tyneside General Hospital
Harton Lane
South Shields
United Kingdom
NE34 0PL

Study participating centre
Musgrove Park Hospital
Parkfield Drive
Taunton
United Kingdom
TA1 5DA

Study participating centre
Derriford Hospital
Derriford Road,
Crownhill,
United Kingdom
PL6 8DH

Study participating centre
Prince Philip Hospital
Bryngwyn Mawr
Llanelli
United Kingdom
SA14 8QF

Study participating centre
John Radcliffe Hospital
Headley Way,
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Churchill Hospital
Old Rd,
Headington
Oxford
United Kingdom
OX3 7LE

Sponsor information

Organisation
Northumbria Healthcare NHS Foundation Trust

Sponsor details
Research and Development Department
North Tyneside General Hospital
North Shields

England
United Kingdom
NE29 8NH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01gfeyd95

Funder(s)

Funder type
Industry

Funder Name
Philips Respironics

Funder Name
Pfizer OpenAir

Results and Publications

Publication and dissemination plan
1. The findings will be disseminated to a broad regional, national and international audience, including respiratory specialists, general physicians and intensive care physicians, through presentations at local, national and international conferences, and publication in high ranking, peer-reviewed, journals. Open access publication fees are included in our application.
2. Locally, we will keep patients, carers, primary and secondary care clinicians, healthcare managers, commissioners and neighbouring healthcare providers informed by publications in existing newsletters and presentations at local and regional meetings, conducted within both NHS organisations and the University. Through established links with the British Lung Foundation (BLF), we will seek to disseminate the results of the study through BLF electronic and published media. We will establish a patient/public group of service users and encourage them to publish the results from the perspective of patients and carers, facilitated by the research team and the BLF.
3. The research team and co-applicants include members (and the chair) of the UK NIV Research Network. We will keep the network and British Thoracic Society COPD Speciality Advisory Group (SAG) and clinical guideline groups informed about the progress and outcome of the study.
4. We will liaise with NHS Improving Quality; the scores developed could be implemented as part of a national service improvement project. A previous study conducted by our group describing the DECAF prognostic score was published in Thorax, awarded several international prizes

recognising its importance and impact, and its use in clinical practice has been recommended by the recent National UK COPD Audit report. We expect similar success in the dissemination and clinical implementation of the results of the proposed study.

Intention to publish date
30/03/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Stephen Bourke at Stephen.bourke@nhct.nhs.uk.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	results presented at American Thoracic Society International Conference	01/05/2020	12/05/2020	No	No
Abstract results	results presented at British Thoracic Society Winter Meeting	01/12/2019	12/05/2020	No	No
Results article		12/08/2021	11/01/2022	Yes	No
Protocol file	version 2.4	19/08/2016	17/08/2022	No	No
HRA research summary			28/06/2023	No	No