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A study comparing home treatment of COPD exacerbations to usual hospital care

Submission date
08/04/2014

Recruitment status
No longer recruiting

Registration date
02/06/2014

Overall study status
Completed

Last Edited
23/04/2020

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] 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 in which patients develop progressive breathlessness, cough and phlegm. Such patients suffer episodes when their symptoms increase, often triggered by infection, called acute exacerbations (AECOPD). AECOPD are the second most common reason for all hospital admissions. There are potential clinical and financial benefits in managing patients at home during exacerbations. Hospital staff with experience of treating unwell patients can deliver most treatments at home that are provided in hospital. It is recommended that patient selection for Hospital at Home (HAH) be based on chance of survival, whilst recognising the lack of a tool for prediction at the time the guideline was written. We then developed a novel, simple clinical scoring system (DECAF) that can predict the survival of patients hospitalised with AECOPD. In this study we aim to find out whether HAH is safe and more cost-effective than hospital admission, whether HAH is the preferred choice for patients and carers, and whether HAH is associated with improvements in health-related quality of life.

Who can participate?
Adults aged 35 or over who are admitted to one of the participating hospitals with an acute exacerbation of COPD and assessed as low risk by the DECAF score can participate. For the qualitative study, patient's carers and healthcare professionals directly involved with caring for patients in the study will be eligible for interview.

What does the study involve?
After obtaining consent, patients will be randomly allocated to be treated for their exacerbation either in the usual way, which involves hospital admission, or to be treated at home. The medical treatment for those patients at home will largely be the same as for those patients in hospital. We will collect clinical information from patients, including their preferred treatment and their health-related quality of life. The costs of the treatment and the costs of social care (including the family carer) will be collected for the economic analysis. This information will be collected from admission up to 90 days. Patients, their carers and healthcare professionals will be approached for interview.

What are the possible benefits and risks of participating?
HAH may foster independence, help maintain usual activities and avoid the complications associated with hospital admission. We do not foresee any risks from participation. Previous studies have shown that home treatment for acute exacerbations of COPD is safe.

Where is the study run from?
1. North Tyneside General Hospital (UK)
2. Wansbeck General Hospital, Ashington (UK)
3. Northumbria Specialist Emergency Care Hospital (UK)

When is the study starting and how long is it expected to run for?
The study started at the end of April 2014 and participants will be recruited over 20 months and followed up for 90 days.

Who is funding the study?
National Institute for Health Research (NIHR), UK.

Who is the main contact?
Carlos Echevarria
CarlosEchevarria@doctors.org.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.10

Study information

Scientific Title
Randomised controlled trial of hospital at home compared to standard inpatient management of patients with an acute exacerbation of chronic obstructive pulmonary disease (AECOPD), triaged for hospital admission by Accident and Emergency and with low mortality risk according to the novel DECAF score

Acronym
HOT DECAF

Study objectives
1. Managing low risk patients at home for acute exacerbations of COPD (AECOPD) is more cost-effective for health and social costs then inpatient management.
2. Patients treated at home for AECOPD have higher health related quality of life scores, and fewer hospital bed days (up to 90 days) compared to those treated in hospital.
3. Patients with AECOPD (and their carers) prefer home treatment to hospital treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North East- Sunderland; 22/10/2013; ref. 3/NE/0275

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Chronic Obstructive Pulmonary Disease

Interventions
Patients will be allocated to hospital at home (HAH) or usual care. Whilst receiving hospital at home, the patient will remain under the care of the hospital team, with 24/7 on-call support. Home treatment will comprise of twice daily respiratory specialist nurse visits supervised by a

respiratory consultant, with additional input from physiotherapy, occupational therapy and formal social care as required.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Health and social care costs over 90 days: non-inferiority analysis.

Secondary outcome measures
1. Survival
2. All cause and respiratory readmission rates
3. Bed days over: a) acute period of care; b) post-discharge to 90 days
4. Carer and patient preference
5. COPD Exacerbations
6. Unplanned health resource use: emergency hospital visits, unscheduled contact with the respiratory specialist nursing team, community based nurse or GP
7. Hospital anxiety and depression score
8. Quality-of-life: COPD Assessment Tool (CAT) and EQ-5D
9. Zarit Burden Interview (carers)
10. Perceptions of healthcare of patients and their carers and health professionals with regards to the use of the DECAF score for allocation to HAH

Overall study start date
29/01/2016

Completion date
02/12/2016

Eligibility

Key inclusion criteria
1. Age ≥35 years
2. Smoking history ≥10 pack years
3. Obstructive spirometry (FEV1/ VC <70%)
4. Primary diagnosis of AECOPD
5. DECAF score 0 or 1

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
118

Key exclusion criteria
Current exclusion criteria as of 26/09/2014:
1. Other illness likely to limit survival to <1 year
2. Long term ventilation
3. Co-existent secondary diagnosis which necessitates admission
4. Acute confusion precluding discharge
5. Assessment more than one overnight stay after admission
6. Lack of ability to give informed consent

Previous exclusion criteria:
1. Other illness likely to limit survival to <1 year
2. Long term ventilation
3. Co-existent secondary diagnosis which necessitates admission
4. Acute confusion precluding discharge
5. Assessment >24 hours after admission
6. Lack of ability to give informed consent

Date of first enrolment
04/06/2014

Date of final enrolment
28/01/2016

Locations

Countries of recruitment
England

United Kingdom

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

Study participating centre
Wansbeck General Hospital
Woodhorn Lane
Ashington
United Kingdom
NE63 9JJ

Study participating centre
Northumbria Specialist Emergency Care Hospital
Northumbrian Road
Cramlington
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NE23 6NZ

Sponsor information

Organisation
Northumbria NHS Foundation Trust (UK)

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c/o Caroline Potts
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01gfeyd95

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme PB-PG-0213-30105

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned submission for publication to Lancet or Respiratory Lancet by January 2017.

Intention to publish date
31/12/2017

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 (Stephen.Bourke@northumbria-healthcare.nhs.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2018		Yes	No
Results article	qualitative results	04/04/2019	23/04/2020	Yes	No