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Multi-centre randomised controlled trial of the early use of non-invasive ventilation in acute exacerbations of chronic obstructive pulmonary disease (COPD)

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
25/02/2010

Condition category
Respiratory

[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
H0020 ELLIOTT R&D

Study information

Scientific Title

Study objectives
Acute exacerbations of COPD are a common reason for hospital admission and are a cause of significant mortality. Non-invasive ventilation (NIV) via a face or nasal mask has been shown to reduce mortality and the need for intubation. However the studies have been carried out in units with a particular expertise in the techniques involved. Instituting NIV in a distressed, dispnoeic individual and matching the ventilator to the patients requirements is difficult. The early introduction of NIV is easier (the patient is better able to cooperate and lower, more comfortable inflation pressures can be used) and may interrupt a vicious cycle of deterioration before it is well established. Moreover simpler ventilations, which do not require great expertise and are therefore practical for use in non-specialist units, can be used. We wish to establish whether early NIV can be widely applied, with benefit, in a variety of hospitals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Respiratory tract diseases: Chronic obstructive pulmonary disease

Interventions
Not provided at time of registration

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
31/12/1996

Completion date
31/12/1998

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
31/12/1996

Date of final enrolment
31/12/1998

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
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United Kingdom
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Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (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	cost effectiveness results	03/05/2003		Yes	No