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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

Protocol serial number
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

Primary study design
Interventional

Study design
Multi-centre randomised controlled trial

Study type(s)
Treatment

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(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

Completion date
31/12/1998

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

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

Sponsor information

Organisation

Funder(s)

Funder type
Government

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