

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

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
23/01/2004	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
23/01/2004	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
25/02/2010	Respiratory	

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, dyspnoeic 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

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?
<u>Results article</u>	cost effectiveness results	03/05/2003		Yes	No