ISRCTN31237955 https://doi.org/10.1186/ISRCTN31237955

# 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
79 Whitehall
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+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

**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 |