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Randomised trial of nasal mask versus full-face mask for the application of non-invasive ventilation in patients admitted to Queen's Medical Centre with an acute exacerbation of chronic obstructive airways disease and hypercapnic respiratory failure

Submission date 12/09/2003	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/09/2003	**Overall study status** Stopped	
Last Edited 17/09/2012	**Condition category** 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

N0192095136

Study information

Scientific Title

Study objectives
Is there any measurable difference in outcome when using a nasal mask versus full-face mask when using bilevel non-invasive ventilation to treat patients with acute exacerbations of chronic obstructive pulmonary disease (COPD) and hypercapnic respiratory failure?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD)

Interventions
Not provided at time of registration

17/09/2012: Please note that this trial was stopped due to a lack of funding

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Improvement of arterial blood gases at 1 h and 4 h, the length of time patients spend on the ventilator in the first 24 h, the comfort of the patient (visual analogue scale) and the survival to discharge.

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

Completion date

01/06/2003

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
Total number of subjects = 50.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
15/01/2002

Date of final enrolment
01/06/2003

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
c/o Dr Kinnear's Secretary
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Queens Medical Centre University Hospital NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration