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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

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

**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
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

### Study design
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
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 measure
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.

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
15/01/2002

### 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

### Age group
Not Specified

### Sex
Not Specified

### Target number of participants
50

### 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

England

United Kingdom

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

# Sponsor information

**Organisation**
Department of Health (UK)

**Sponsor details**
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

**Sponsor type**
Government

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

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Queens Medical Centre University Hospital NHS Trust (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