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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr WJ Kinnear

Contact details

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Additional identifiers

Protocol serial number

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

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

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