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Influence of respiratory efforts on b2-agonist induced bronchodilation in mechanically ventilated COPD patients

Submission date 20/07/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/07/2005	**Overall study status** Completed	
Last Edited 25/09/2009	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
The aim of our study was to examine the influence of controlled and assisted modes of ventilatory support on the bronchodilative effect induced by b2-agonists administered with a metered-dose inhaler (MDI) and a spacer in a homogeneous group of patients with acute exacerbation of chronic obstructive pulmonary disease.

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)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Acute exacerbation of chronic obstructive pulmonary disease

Interventions
All patients were intubated with an endotracheal tube 8-9 mm in internal diameter, sedated (propofol and remifentanyl) and initially ventilated (for 24 to 36 hours) on volume-controlled (VC) mode using settings that minimized dynamic hyperinflation. After this period, the patients were switched to flow-triggering pressure-support (PS) ventilation with the level of pressure assist adjusted to obtain a tidal volume (VT) of 7-10 ml/kg. Extrinsic positive end-expiratory pressure (PEEP) of approximately 1-2 cmH2O lower than PEEPi, measured on controlled mode, was applied. The threshold for triggering was set to 2 l/min. Propofol and remifentanyl infusions during VC and PS mode were titrated such as to obtain sedation levels 6 and 3 on the Ramsey scale respectively. If patients were stable on PS with adequate gas exchange, respiratory frequency less than 30 breaths/min and without clinical evidence of excessive work of breathing, all bronchodilators were withheld for 6 hours. By the end of this period patients were re-evaluated and if they had a respiratory frequency of less than 30 breaths/min, adequate gas

exchange and no clinical evidence of excessive work of breathing they were prospectively randomized to receive 4 puffs of salbutamol (S, 100 µg/puff given by an MDI canister, Aerolin inhaler, GlaxoWellcome) being ventilated either on PS or VC mode. On VC mode, VT and ventilator frequency were set to values similar to these on PS. A square wave flow pattern was used and no end-inspiratory pause time was applied. No manipulation was performed on PS. After a six hour washout-period, the patients were crossed-over to receive the drug by the alternative mode of ventilation. The MDI was adapted to the inspiratory limb of the ventilator circuit using an aerosol cloud enhancer spacer (ACE, Diemolding Healthcare Division, USA), whereby the MDI flume is directed away from the patient. The spacer was placed just before the Y-ventilator connector. The canister was shaken before each series of puffs. Each actuation was performed at 20 to 30 sec intervals, immediately before initiation of airflow by the ventilator on VC or before the sudden drop in airway pressure on PS, which signaled the start of the triggering process. Arterial blood gases were measured before and 4 hours after drug administration. SaO2 was measured continuously using a pulse oxymeter (Critikon, Tampa, FLA, USA).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Salbutamol

Primary outcome measure
Respiratory system mechanics (Resistance)

Secondary outcome measures
Heart rate, arterial blood gasses

Overall study start date
01/03/2003

Completion date
01/11/2003

Eligibility

Key inclusion criteria
Patients with chronic obstructive pulmonary disease (COPD), requiring endotracheal intubation and mechanical ventilation to manage acute respiratory failure due to an acute exacerbation of chronic airflow obstruction, were studied. All patients had a previous diagnosis of COPD and met established criteria for this diagnosis.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
10

Key exclusion criteria
Hemodynamically unstable

Date of first enrolment
01/03/2003

Date of final enrolment
01/11/2003

Locations

Countries of recruitment
Greece

Study participating centre
ICU
Heraklion, Crete
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Sponsor information

Organisation
University of Crete, Medical School (Greece)

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Sponsor type
University/education

ROR
https://ror.org/00dr28g20

Funder(s)

Funder type
Not defined

Funder Name
None

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	results	01/02/2007		Yes	No