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The use of nebulised magnesium sulphate in exacerbations of chronic obstructive pulmonary disease

Submission date	Recruitment status	[ ] Prospectively registered
24/10/2006	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/12/2006	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/01/2011	Respiratory	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2006-002484-99

Protocol serial number
2006-002484-99

Study information

Scientific Title

Study objectives
To examine whether adjuvant magnesium therapy administered via nebuliser is effective in the management of patients with acute exacerbations of Chronic Obstructive Pulmonary Disease (COPD).

Null Hypothesis: In patients with COPD, there is no difference in Forced Expiratory Volume in One second (FEV1) (primary outcome) between those given salbutamol with adjuvant magnesium sulphate and those given treatment as usual (salbutamol alone).

Ethics approval required
Old ethics approval format

Ethics approval(s)
North & East Devon REC (ref: 06/Q2102/80) provisional approval subject to minor amendments 17/10/06.

Study design
This is a double-blind, randomised, placebo-controlled study comparing adjuvant nebulised magnesium therapy with standard Emergency Department (ED) treatment of acute exacerbations of COPD.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic Obstructive Pulmonary Disease (COPD)

Interventions
1. Control Arm: Salbutamol (2.5 mg in 2.5 ml) diluted in Normal Saline 2.5 ml to make up a 5 ml solution (placebo).
2. Experimental Arm: Salbutamol (2.5 mg in 2.5 ml) diluted in isotonic magnesium (2.5 ml of 0.25 mmol/ml [61.75 mg/ml] magnesium) to make up a 5 ml solution for nebulisation.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Magnesium sulphate, salbutamol

Primary outcome(s)
1. Forced expiratory volume in one second (FEV1)

Key secondary outcome(s))
1. Forced Vital Capacity (FVC)
2. Discharge within 48 hours
3. Risk of requiring NIV or intubation or escalation of treatment
4. Length of hospital stay - days
5. Arterial blood gas tensions
6. Modified Borg score

Completion date
01/11/2007

Reason abandoned (if study stopped)
Participant recruitment issues

Eligibility

Key inclusion criteria
1. 35 to 80 years old
2. Diagnosis of COPD as defined by the American Thoracic Society
3. Presentation to the ED with an acute exacerbation of COPD
4. FEV1 less than or equal to 70%
5. FEV1/Forced Vital Capacity (FVC) ratio less than 70%
6. 20 pack year smoking history

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

Key exclusion criteria
1. Patients requiring intubation, Non-Invasive Ventilation (NIV) or too severe to perform spirometry
2. Arterial pH less than 7.32
3. Clinical history of asthma
4. Known cardiac disease, chronic renal insufficiency or other serious medical condition
5. Pregnant women
6. Clinical or radiographic evidence of pneumonia
7. Hypotension (systolic blood pressure less than 100 mmHg)

Date of first enrolment
01/11/2006

Date of final enrolment

01/11/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Heart & Lung Unit
Torquay
United Kingdom
TQ2 7AA

Sponsor information

Organisation
South Devon Healthcare NHS Trust (UK)

ROR
https://ror.org/05374b979

Funder(s)

Funder type
Charity

Funder Name
Torbay Medical Research Fund (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration