

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

Submission date 24/10/2006	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/12/2006	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/01/2011	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

EudraCT/CTIS number

2006-002484-99

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

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 measure

1. Forced expiratory volume in one second (FEV1)

Secondary outcome measures

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

Overall study start date

01/11/2006

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

Age group

Adult

Sex

Not Specified

Target number of participants

100

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**

England

United Kingdom

Study participating centre**Heart & Lung Unit**

Torquay

United Kingdom

TQ2 7AA

Sponsor information**Organisation**

South Devon Healthcare NHS Trust (UK)

Sponsor details

c/o R&D Department

Torbay Hospital

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United Kingdom

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+44 (0)1803 655039

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Sponsor type

Hospital/treatment centre

Website

<http://www.sdhct.nhs.uk/>

ROR

<https://ror.org/05374b979>

Funder(s)

Funder type

Charity

Funder Name

Torbay Medical Research Fund (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