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Prevention of Atrial Arrhythmias by Infusion of Magnesium Sulphate after Lung Resection for Cancer

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 02/08/2012	**Condition category** Cancer	

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
N0054186615

Study information

Scientific Title

Study objectives
We hypothesize that the prophylactic infusion of magnesium sulphate significantly reduces incidences of postoperative atrial fibrillation in patients undergoing thoracotomy, pneumonectomy and lobectomy.

This is a single-centre, controlled and randomised clinical trial. Study patients will be recruited into the trial from participating surgeons waiting lists and those consenting for the trial will be included in the trial register. Atrial arrhythmias are common after pulmonary procedures with reported incidences ranging from 10% to 20% after lobectomy and up to 40% after pneumonectomy. To date only one randomised study published nearly a decade ago showed that postoperative atrial tachyarrhythmias, mainly atrial fibrillation could be significantly reduced when magnesium sulphate was administered. A general consensus is still lacking on the efficacy of magnesium sulphate as anti-arrhythmic drug for patients undergoing lung cancer operation. We plan to investigate in this by carrying out a randomised, parallel, blinded, controlled trial involving a total of 240 patients (n=120 per group).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single-centre controlled and randomised clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Cancer: Lung

Interventions

Patients will be randomly allocated in equal numbers to treatment with or without magnesium sulphate and followed-up during the in-hospital perioperative period.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Magnesium Sulphate

Primary outcome measure
Atrial fibrillation will be assessed using a standard 12-lead ECG measurement from the onset of the Q wave to the end of the S wave.

Secondary outcome measures
1. Myocardial Infarction will be defined by two of the following three criteria if present: Unequivocal ECG changes. Elevation of cardiac enzyme(s): 3 times upper limit of creatinine kinase CK/CKMB) and above twice the upper limit of normal or elevated troponin (T/I). Chest pain typical of ischaemia lasting for more than 20 minutes.
2. Respiratory complications as determined by the requirement for postoperative mechanical ventilation greater than 24 hours or reintubation for ventilatory support after the day of surgery; pneumonia - defined as fever eukocytosis, pulmonary infiltrate requiring antibiotic therapy; air leak from thoracostomy tubes for more than six days postoperatively; lobar collapse on postoperative chest radiograph; empyema and bronchopleural fistula. Sputum retention defined as failure to clear bronchial secretions that can result in: bronchial obstruction, atelectasis, lobar collapse, secondary pulmonary infection.
3. Renal Complications - postoperative rise in serum creatinine above 200µmol/litre or requirement of postoperative dialysis support in a patient with normal preoperative renal function was considered to be a renal complication.
4. Neurological complications - a postoperative new cerebrovascular accident or transient ischaemic attack was considered to be a neurological complication.
5. Pulmonary embolus defined as a blockage of an artery in the lungs by fat, air, tumor tissue, or blood clot.
6. Death is defined as all-cause mortality and the cause of death will have to be specified. In the analysis, all deaths during the study period will be compared between the two groups.

Overall study start date
01/09/2006

Completion date
01/09/2008

Eligibility

Key inclusion criteria
240 subjects will be recruited. The investigator will be responsible for screening all patients listed for lung surgery at the CTC. Evidence from Terzi et al [32], had demonstrated that incidences of AF occurred in 10.7% of patients on magnesium sulphate as compared with 26.7%

of control patients. We predict that at 90% power (2-sided ¿=0.05), 240 patients allowing for drop outs, deaths etc) are required to detect at least a 16% reduction in incidences of AF.
Inclusion Criteria:
1. Elective for non-cardiac thoracic operations for lung cancer (lobectomy and pneumonectomy)
2. Ability to provide informed consent

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
240

Key exclusion criteria
1. Patients not undergoing major lung resection (see above)
2. Impaired renal function, preoperative creatinine >200 mol/L
3. Myocardial infarction within the last 6 months
4. Urgent or emergency operations
5. Video assisted thoracic surgery
6. Currently on drugs with antiarrhythmic properties
7. Patients with a history of preoperative cardiac arrhythmias

Date of first enrolment
01/09/2006

Date of final enrolment
01/09/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Thoracic Surgery
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

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Sponsor type
Government

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Funder(s)

Funder type
Government

Funder Name
The Cardiothoracic Centre Liverpool NHS Trust (UK), NHS R&D Support Funding

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