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Magnesium sulphate for the prevention of supra-ventricular dysrhythmia following non-cardiac thoracic surgery

Submission date	Recruitment status	[_] Prospectively registered
11/06/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/07/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/08/2013	Circulatory System	

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)
2004-002818-11

Protocol serial number
Version 5

Study information

Scientific Title

Acronym
MAGNETS

Study objectives
The prophylactic perioperative correction of magnesium deficiency by infusion of magnesium sulphate to all patients presenting for thoracotomy or thoracolaparotomy for pneumonectomy, lobectomy or oesophagectomy will significantly reduce the incidence of supra-ventricular dysrhythmias post operatively.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Birmingham Research Ethics Committee. Date of approval: 04/05/2005 (ref: 05/Q2707/1)

Study design
Single-centre prospective double-blind randomised placebo-controlled study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Supra-ventricular dysrhythmias in patients following non-cardiac thoracic surgery

Interventions
Patients are randomised into either the placebo or magnesium groups. Patients receive either placebo or 5 g magnesium sulphate infusion intra-operatively, day 1 and day 2 post-operatively. Continuous electrocardiogram (ECG) recording for 5 days will be commenced using a holter (non-invasive) recorder after induction of anaesthesia. ECG data will be analysed by a cardiac physiologist who is blinded from which treatment group the patient is in.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome(s)

To demonstrate a clinically and statistically significant reduction in the incidence of postoperative supra-ventricular dysrhythmias in the patient group who have received magnesium in comparison to the placebo group. It is aimed that patients have holter monitoring for 5 days post-operatively.

Key secondary outcome(s))
1. Length of hospital stay
2. Thirty-day mortality

Completion date
30/06/2008

Eligibility

Key inclusion criteria
1. Both male and female patients
2. Above 18 years; no upper age limit
3. Patients presenting to the Department of Thoracic Surgery at Birmingham Heartlands Hospital for elective lobectomy, bi-lobectomy, pneumonectomy or oesophagectomy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Evidence of renal failure (serum creatinine of >130)
2. Liver failure
3. Pre-existing cardiac arrhythmia
4. Undergoing long-term treatment for an arrhythmia
5. On long-term treatment with nifedipine or aminoglycosides
6. Known hypersensitivity to magnesium sulphate
7. If preoperative magnesium level is equal or greater than 1.2 mmol/l
8. If they are unwilling or unable to give informed consent for their participation or if they withdraw consent
9. Patients who have participated in another interventional study within the previous 3 months

Date of first enrolment
01/06/2006

Date of final enrolment
30/06/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
2nd Floor
Birmingham
United Kingdom
B5 5SS

Sponsor information

Organisation
Heart of England NHS Foundation Trust (UK)

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation (UK)

Alternative Name(s)
The British Heart Foundation, the_bhf, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
European Association of Cardiothoracic Anaesthesiologists (EACTA) (Ireland)

Results and Publications

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	01/06/2011		Yes	No