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Efficacy of magnesium and sotalol in prevention of Atrial fibrillation (AF) following cardiac surgery

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 01/04/2020	**Condition category** Circulatory System	

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
N0054131771

Study information

Scientific Title
Efficacy of magnesium and sotalol in prevention of Atrial fibrillation (AF) following cardiac surgery

Study objectives
We aim to study the efficacy of this combination of sotalol and magnesium in more clinically common patient groups like patients undergoing valve surgery, impaired left ventricular (LV) function and borderline respiratory function which makes it more useful to our patient population and hence our practice. This study will be unique from previous studies in that it looks at more patients who are in-line with our day to day practice and also analyses the heretofore most efficient and least complicating change in cardiac surgery and ensure shorter hospital stay and better patient care. The economic implications of 25% of patients treated for atrial fibrillation and good proportion going on to have lifelong treatment with or without warfarin is quite obvious.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised double-blind controlled study

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
Cardiovascular: Atrial fibrillation (AF)

Interventions
2 groups - a control group given placebo and a study group given sotalol with magnesium.

Preoperative assessment of electrocardiogram (ECG), serum potassium and magnesium levels. ECG repeated on postoperative days, 1, 2, 4, 7 and 6 weeks. QTc noted for the ECGs. Serum potassium and magnesium are measured every day for seven days. Drugs administered: Sotalol 80 mg twice daily started on first postoperative day and continued for five days and decreased

to 40 mg twice daily for the next six weeks and then terminated. If the patients heart rate slows down to less than 50 beats per minute when on a 80 mg dose then the dose is decreased to 40 mg twice daily even if its earlier than five days. Magnesium 4 g intravenously first dose given when patient arrives in intensive therapy unit (ITU), second dose of 4 g is given post operatively 24:00 hrs on the night of procedure in the intensive care. This is followed by magnesium sulphate 4 g intravenously twice daily for the next two days.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Magnesium and sotalol

Primary outcome measure
1. To monitor the frequency of atrial fibrillation following pre-operative treatment with sotalol and magnesium and to determine its efficacy in a large group of cardiac surgery patients.
2. The prevention of Atrial Fibrillation in patients undergoing Cardiac Surgery

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/12/2003

Completion date
01/05/2004

Eligibility

Key inclusion criteria
Therapeutic research: All patients admitted for cardiac surgery in The Cardiothoracic centre are potential participants. All the details of the study are explained to the patients and a patient information sheet is given to them. Following this, a proper consent is obtained.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
98 patients per group needed to detect a reduction in AF rate to 10% at 90% power, therefore 200 patients (100 per group) will be recruited.

Key exclusion criteria
1. Patients who are in another trial that might have a bearing or influence in outcome in this study
2. Patients undergoing aortic procedure, preoperative atrial fibrillation or second or third degree heart block and patients with preoperative creatinine value of more than 200.

Date of first enrolment
01/12/2003

Date of final enrolment
01/05/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Liverpool NHS Trust
Liverpool
United Kingdom
L14 3PE

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Cardiothoracic Centre Liverpool NHS Trust (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