

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

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		<input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 01/04/2020	Condition category Circulatory System	<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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised double-blind controlled study

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Liverpool NHS Trust

Liverpool

United Kingdom

L14 3PE

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

The Cardiothoracic Centre Liverpool NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration