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Comparison of elective early direct current (DC) cardioversion vs oral amiodarone in the treatment for new post-operative atrial fibrillation in patients undergoing coronary artery bypass grafting (CABG): a prospective randomised controlled study

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 14/11/2014	**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
N0054123058

Study information

Scientific Title

Study objectives
Elective DC cardioversion is one of the modalities of treating new atrial fibrillation. The procedure is deemed relatively safe, and immediately effective in most instances. However, there have been few studies comparing the results of early elective DC cardioversion with the results of the use of anti-arrhythmic drugs only as primary modalities of treatment for this condition, and the implications this may have on the incidence of heamodynamic compromise, thrombo-embolic events and hospital stay. The results of this study will help us in making the choice about the safest, quickest and most appropriate modality of treatment for these patients, and this would have favourable implications on patient outcome and duration of hospital stay.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular: Atrial fibrillation (AF)

Interventions

First time CABG patients who develop atrial fibrillation in the post-operative period following discharge from intensive care will be randomly assigned to one of two groups. Group one will be administered oral amiodarone and group two will receive DC cardioversion in addition to oral amiodarone. Daily electrocardiogram (ECG) will document heart rhythm. A blinded independent researcher will interpret the ECG on the day of discharge.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Patient's cardiac rhythm at discharge

Secondary outcome measures
1. Duration between onset of atrial fibrillation and reversion to sinus rhythm
2. Duration of hospital stay
3. Patient's rhythm on outpatient follow-up at 6 weeks postoperatively

Overall study start date
08/05/2003

Completion date
01/05/2005

Eligibility

Key inclusion criteria
400 first time CABG patients who develop atrial fibrillation in the post-operative period following discharge from intensive care will be randomly assigned to one of two groups.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
400

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
08/05/2003

Date of final enrolment
01/05/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Cardiac Surgery
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
Government

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