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# The role of high dose statins in the prevention of postoperative atrial fibrillation in patients undergoing cardiac surgery

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| **Submission date**<br>14/08/2006 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>21/09/2006 | **Overall study status**<br>Completed | |
| **Last Edited**<br>14/12/2010 | **Condition category**<br>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
N/A

# Study information

### Scientific Title

### Study objectives
1. Perioperative treatment with high dose atorvastatin (80 mg once daily) reduces the occurrence of Atrial Fibrillation (AF) following cardiac surgery in the early postoperative period.
2. Perioperative treatment with atorvastatin prevents irreversible perioperative myocardial injury.
3. Metabolic derangements may explain the increased energy demand during AF.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Ethical approval has been obtained for this study from the Wandsworth Local Research Ethics Committee (reference number: 06/Q0803/37). The study has been registered with the Clinical Trials Unit.

### Study design
Prospective analysis, randomised, double-blind 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
Atrial fibrillation

### Interventions
We propose to carry out a randomised, double-blind study of the effect of atorvastatin 80 mg, or placebo on postoperative AF in 450 patients undergoing cardiac surgery. Patients of all ages will be included and those in sinus rhythm will be chosen. Inflammatory markers including C-Reactive Protein (CRP), Matrix MetalloProteinase (MMP) and its inhibitor, will be measured. Both right and, where possible, left atrial tissue will be studied for proteomic analysis. AF will be documented by continuous monitoring in the postoperative period.

The patients will be randomised to the following groups:
1. Patients on statins will be randomised to 10 mg and 80 mg of atorvastatin
2. Patients taking no statins will be randomised to placebo and 80 mg of atorvastatin

The treatments will continue for one week following surgery. Patients will be evaluated in an assessment clinic one week prior to surgery and will be randomised to one of the two groups. If patients have already been on any of the statins, that will be stopped in the clinic.
Randomisation will be performed by the Clinical Trials Unit using a minimisation algorithm. All patients will have a trans-thoracic echocardiography performed prior to surgery determining the size of the atria, right and left ventricular function and evidence of thrombo-embolism.

### Intervention Type
Drug

### Phase
Not Specified

### Drug/device/biological/vaccine name(s)
Atorvastatin

### Primary outcome measure
Atrial fibrillation

### Secondary outcome measures
Thromboembolic episodes (Transient Ischaemic Attacks [TIA]/CerebroVascular Accident [CVA])

### Overall study start date
18/09/2006

### Completion date
17/09/2007

## Eligibility

### Key inclusion criteria
Patients undergoing elective first time Coronary Artery Bypass Graft (CABG) and/or Aortic Valve Replacement (AVR) will be randomised.

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
450 patients undergoing elective first time CABG and/or AVR

### Key exclusion criteria
1. History of atrial arrhythmias
2. Hepatobiliary disease
3. Creatinine more than 180 mmol/l
4. Known intolerance of statins
5. Patients on long-term inhibitors of cytochrome P-450, history of AF, patients on treatment for anti-arrhythmic agents, except those on betablockers

### Date of first enrolment
18/09/2006

### Date of final enrolment
17/09/2007

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Department of Cardiac Surgery**
London
United Kingdom
SW17 0QT

## Sponsor information

### Organisation
St. George's Hospital Charitable Foundation (UK)

### Sponsor details
Bronte House
St. George's Hospital
Blackshaw Road
London
United Kingdom
SW17 0QT

### Sponsor type
Charity

### Website
http://www.stgeorges.nhs.uk

**ROR**
https://ror.org/0001ke483

# Funder(s)

**Funder type**
Charity

**Funder Name**
St. George's Hospital Charitable Foundation

# 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

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/01/2011 | | Yes | No |