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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
14/08/2006		☐ Protocol		
Registration date 21/09/2006	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
14/12/2010	Circulatory System			

## 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** 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

## Study type(s)

Treatment

## 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(s)

Atrial fibrillation

## Key secondary outcome(s))

Thromboembolic episodes (Transient Ischaemic Attacks [TIA]/CerebroVascular Accident [CVA])

## 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

## Healthy volunteers allowed

No

## Age group

Adult

## Sex

All

## 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

**United Kingdom** 

England

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

# Sponsor information

## Organisation

St. George's Hospital Charitable Foundation (UK)

### **ROR**

https://ror.org/0001ke483

# Funder(s)

## Funder type

Charity

## **Funder Name**

St. George's Hospital Charitable Foundation

# **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	01/01/2011		Yes	No